



## Education for children, young people and families living with diabetes

### **Information for parents about the research**

We would like to invite you and your son/daughter to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of the study and what will happen to you and your child if you take part. Part 2 gives you more detailed information about the conduct of the study)

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

#### ***Part one:***

##### ***What is the purpose of this study?***

This study is testing different ways of teaching children and their parents how to live with their diabetes, and how to manage diabetes together and keep it well controlled.

##### ***Why have we been invited?***

You have been invited because your child is between 8 and 16 years of age, has diabetes, and is attending a clinic that is taking part in this study.

##### ***Do we have to take part?***

No. It is up to you to decide. A researcher from the University of London will describe the study and go through this information sheet with you, which will then be yours to keep. If you are willing to participate, we will then ask you to sign a consent form to show you have agreed that you and your child will take part. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care your child receives.

##### ***What will happen to us if we take part?***

All clinics aim to teach children and their parents how to manage their diabetes. This study is comparing different ways of teaching this information to families. All the ways of teaching have potential advantages and disadvantages. By doing this study we will be able to determine which approach is better.

How clinic staff provide this information to you will depend on which education programme is being used at your clinic. Some clinics ask children and parents to attend separate sessions in addition to their usual clinic appointments to be taught this information; others offer information during your usual clinic appointments. The clinics have been chosen by chance to offer the different ways of teaching information. If your clinic offers this information in separate sessions, this will mean that you and your child will be asked to attend four separate sessions, lasting 2 to 3 hours each, as well as your usual appointments. The separate sessions are spread over three to four months. They will be attended by three or four families with children of a similar age. If your clinic offers information during your usual clinic appointments you will continue to attend clinics as before.

All children and parents taking part in the study, however they are taught about living with diabetes' will be asked about the clinic education programmes and how they look after and live with their diabetes. You and your child will be given a questionnaire to complete, with the help of a researcher, when you join the study, and one year and two years later. Some children and their parents will also be invited to attend a focus group to discuss the education programme at the clinic. The travel costs of attending the focus group will be paid by the study.

On joining the study your child will need to have a sample of blood taken from their vein to test their diabetes control. This test is part of your child's usual care, however, in some clinics it is done by having the blood taken by a pin prick from the finger. The blood sample from the vein will be repeated at 12 and 24 months after you agree to take part in the study. Other blood samples will be taken using the method normally used by your clinic as part of usual care.

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### **What are the possible benefits of taking part?**

We cannot promise that the study will help you but the information we get from this study might help improve care for children with diabetes.

### **What happens when the study stops?**

The study lasts for four years, beginning in March 2008. Separate education sessions shared with other families last four months near the beginning of the study. Your child's care will not be interrupted by the end of the study.

### **What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information is given in part 2.

### **Will my taking part in the study be kept confidential?**

Yes. We shall follow ethical and legal practice and all information about you will be handled in confidence. The details are included in part 2.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making a decision.

## **Part two:**

### **What if relevant new information becomes available?**

Sometimes we get new information about the treatment being studied during the course of a research study. If this happens, your clinic doctor will tell you and discuss whether you and your child should continue in the study. If you decide not to carry on, your clinic doctor will make arrangements for your care to continue. If you decide to continue in the study your clinic doctor may ask you to sign an updated consent form.

If this happens, your clinic doctor might consider if you should withdraw from the study. He/ she will explain the reasons and arrange for your child's care to continue.

If the study is stopped for any other reason, we shall tell you and arrange your child's continuing care.

### **What happens if I don't want to carry on with the study?**

You can withdraw from the education programme at any time, although any information already collected may still be used. Stored blood samples that can be identified as your child's will be destroyed if you wish. Even if you withdraw from the education programme, we would still like to keep in contact with you about your child's progress, if you are willing.

### **What if there is a problem?**

If you have a concern about any aspect of the study, you should ask to speak to the researcher or project manager who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your clinic.

In the event that something does go wrong and you or your child are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation from University College London Hospital NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **Will our taking part in this study be kept confidential?**

All information which is collected about you and your child during the course of the research will be kept strictly confidential. It will be shared with associated university researchers who have a duty to you and your child as research participants. If you or your child were to disclose issues related to child protection during the research, we might have to divulge this information

to an appropriate person. We would discuss this with you before we notified anyone else.

With your permission, we will let your GP know that your child is taking part in the study.

It would also be very helpful if you would agree that your name could be registered with the NHS Central Register. This would make it easier for the study team to contact you in the future, even if you move house.

### **What will happen to any samples my child gives?**

Blood taken at the beginning of the study and at 12 and 24 months will be sent to a central laboratory. Samples will be identified with an anonymised code number. The results will be fed back to you by your clinical team.

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

The results of the research study will be published in a report that will be available on the World Wide Web, and in journal articles. You and your child will not be identified in any report or publication. A summary of the report will also be available to you and your child through your clinic.

### **Who is organising and funding the research?**

The NHS Research and Development programme will pay your child's clinic for including you and your child in this study.

### **Who has reviewed this study?**

All research in the NHS is looked at by independent groups of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the National Ethics Service Committee

### **Further information and contact details**

If you would general information about research please contact Carol Vigurs on 0207 612 6613 or [c.vigurs@ioe.ac.uk](mailto:c.vigurs@ioe.ac.uk)

If you would like to know more about this study, please contact Carol Vigurs on 0207 612 6613 or [c.vigurs@ioe.ac.uk](mailto:c.vigurs@ioe.ac.uk)

If you would like to discuss with someone whether or not you should participate a member of the research team will be present at your next clinic appointment.

If you are unhappy with this study please contact Carol Vigurs on 0207 612 6613 or Dr Vicki Strange on 0207 612 6731 or [v.strange@ioe.ac.uk](mailto:v.strange@ioe.ac.uk)

**Thank you for reading this – please ask any questions if you need to.**