

PARENT INFORMATION SHEET



The FLASH Study (flash glucose monitoring in children and young people with type 1 diabetes).

You and your child are being invited to take part in a study providing feedback about the FreeStyle Libre glucose monitoring sensor. We want to know more about families' views and experiences of FreeStyle Libre, so we can make recommendations to parents and children in the future that might be helpful to their diabetes care.

This information sheet provides details about the study and explains what taking part would involve. Please take time to read it carefully and discuss with others if you wish.

Why have I and my child been invited to take part?

We would like to speak with parents of children and young people aged 5-18 years, who use FreeStyle Libre and also to some who were introduced to it but decided not to carry on using it, or not to start using it. We are also inviting young people between the ages of 8 and 18 years to give their feedback and experience of FreeStyle Libre. We hope to get feedback from around 15-20 families in this study.

Do we have to take part?

It's up to you and your child to decide to join the study. You or your child are free to stop taking part at any time during the study without giving a reason.

Contact details?

If you or your child is interested in taking part please contact the research team by email or phone:

Email: flash-study@bristol.ac.uk

What will happen if we take part?

- We will arrange a time to talk to you by video call, using a computer, tablet (iPad), or by phone.
- We will ask you and your child to take part in a brief discussion either together or separately depending on your preference (lasting around 30-45 minutes) to ask questions about what you think of FreeStyle Libre.
- We will ask you and your child if it's OK for us to make an audio recording and a written transcript of our discussion. We will remove all names from these so that you cannot be identified. You can choose to have the video option on Zoom/Skype switched on or off.
- We may want to use quotes from the discussions so we can tell doctors, nurses and other researchers about your experiences of FreeStyle Libre. We will remove all names from these quotes, so they are anonymous.

How will we use information about you?

We will need to use information that you provide about yourself for this research project. This information will include your [name and contact details]. People will use this information to do the research or to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

If you or your child tell us something that makes us worried about your safety, we may have to discuss this with somebody else as we need to be sure you are safe, but we will talk to you or your child about this first.

If you decide to take part you will be emailed a copy of your consent, and your child's assent form to keep. If your child is aged 16-18 years and they provide an email address, we will email a copy of their consent form directly to them. The handling, processing, storage, and destruction of these data will be compliant with the Data Protection Act 2018 and General Data Protection Regulations.

Once we have finished the study, we will keep some of the data so we can check the results. At the end of 5 years we will destroy all the information we collect from the project.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- 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.
- Written transcripts of the discussion will be used only for this research project, unless you and your child give permission for them to be used for future research and teaching via the consent form.

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.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- by asking one of the research team
- by sending an email to: data-protection@bristol.ac.uk, or
- by calling the University's Data Protection Officer on (0117) 3941824.

What will you do with the results of the study?

Once the data have been analysed, we will seek to share our findings through publication, presentation and the media. All reports will be written in a way that ensures that no-one can work out that you took part in the study. We will give feedback to anyone who takes part in the study via our University of Bristol website.

What are the possible benefits of taking part?

We cannot promise that the study will help you or your child, but we hope that the information you provide will help other young people with type 1 diabetes in the future to manage their condition more effectively. Some young people like to know that they are helping others in the future. Your child may also learn about research.

What are the possible disadvantages and risks of taking part?

Apart from the time required for the discussions, there are unlikely to be disadvantages. You can choose to stop the discussion at any stage. If the discussion raises any worries or anxieties for you or your child, please discuss them with the research team. With your permission, the research team can contact the lead study consultant at your child's hospital, who will arrange a discussion with a health care specialist within the diabetes team about any worries or anxieties raised. We have also included details below of organisations that offer support and information for children with type 1 diabetes and could provide help:

Diabetes UK: diabetes.org.uk/how_we_help/helpline
Juvenile Diabetes Research Foundation: jdrf.org.uk/information-support

Who can I speak to if I have any concerns about the study?

If you have any concerns about the study you may speak to the researchers [Rebecca Kandiyali](#) or [Lucy Beasant: \[flash-study@bristol.ac.uk\]\(mailto:flash-study@bristol.ac.uk\)](#) If you need to complain about the study, please contact [University of Bristol Research Governance and Ethics: \[research-governance@bristol.ac.uk\]\(mailto:research-governance@bristol.ac.uk\)](#)

Who is organising and funding the research?

This study is being carried out by researchers at the University of Bristol. The work is funded by the National Institute for Health Research (NIHR), Research for Patient Benefit, NIHR201085.

Research Team

- [Dr Rebecca Kandiyali](#), Research Fellow
- [Dr Lucy Beasant](#), Senior Research Associate

Who has reviewed the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This project has been checked by The Faculty of Health Sciences Research Ethics Committee at the University of Bristol.

The University of Bristol has arranged insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University. This does not in any way affect an NHS Trust's responsibility for any clinical negligence on the part of its staff (including the Trust's responsibility for University of Bristol employees acting in connection with their NHS honorary appointments).

**THANK YOU FOR READING
THIS INFORMATION SHEET.**