PARTICIPANT INFORMATION SHEET

Type 1 Diabetes TrialNet Protocol TN-16

Long-Term Investigative Follow-Up in TrialNet (LIFT)

You (you means you or your child) recently completed participation in a TrialNet study. As you know, TrialNet is an international research group dedicated to the study, prevention, and early treatment of type 1 diabetes.

Why have I been invited?
You were either in a TrialNet study before you were diagnosed with type 1 diabetes, or you were in a TrialNet study that started soon after you developed diabetes. These studies have provided important information about how diabetes develops and the effects of different therapies.

What is the purpose of the study?
You are now being asked to participate in a follow-up study so that we can continue to learn from you.

We hope to learn

- whether there are long-term effects of any experimental treatment you may have received.
- whether participating in a TrialNet study has affected what happens to your diabetes over time whether or not you received experimental therapy.

We are particularly interested in finding out about your general health, your diabetes, and how much insulin you make over time.

This participant information sheet tells you about the study and what you will be asked to do. The study will be explained to you and you

will be given the chance to ask questions. Taking part in this study is your decision.

Do I have to take part?

Taking part is voluntary. It is up to you to decide whether or not to take part. If you do decide to take part we will ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep. If you decide to take part you are still free to withdraw at any time. If you decide not to take part you do not have to give a reason, nobody will be upset and the standard of care you receive will not be affected.

What will happen to me if I take part?

If your previous study results show that you are still making insulin you will be asked to come in every six months to measure your insulin secretion. Insulin secretion is measured by an Oral Glucose Tolerance Test (OGTT) or a Mixed Meal Tolerance Test (MMTT). An OGTT involves drinking a sweet drink then having blood taken at regular intervals over 2 hours. An MMTT is a similar test, but you will need to drink a milkshake like drink at the start of the test. There is more information about this on page 3.

For those in TrialNet studies **before** their diagnosis of diabetes, you will be asked to do either an OGTT *or* an MMTT at study visits. At the visit one year after your diagnosis, you will be asked to do both tests. These will be done on two separate days.

For those who started in a TrialNet study **after** diagnosis, you will be asked to do a MMTT at each study visit.

At any time we may find that you no longer make insulin, you then will not be asked to do any further OGTT or MMTT testing. You will just be contacted annually. We may be able to arrange for you to have a blood sample taken at a location convenient to you.

For all participants, the blood samples will be used to measure HbA1c and do other studies to learn about your general health and immune system. We will also ask you questions about your diabetes management and general health.

All together, the studies will require about 2 tablespoons of blood in adults. Less blood may be taken from children depending upon their

age and weight. The total amount of blood drawn for tests at each visit will not exceed limits that are safe for your age and weight. Each visit will take 2-3 hours. Blood will not be taken from women who are pregnant as this may affect the test results.

What happens during each test?

- **MMTT and OGTT**

You will need to be fasting on the day of your test. Before each MMTT or OGTT, you will get special instructions about diet and insulin dosing. To make the blood sampling easier for the test, an intravenous needle and plastic tube (IV) will be placed in your vein. The IV will be kept in place during the test. Two blood samples taken ten minutes apart (one teaspoon of blood for each sample) will be taken through the IV. You will then drink either a sweet liquid that contains glucose for the OGTT, or a milkshake like drink called Boost which has glucose as well as fats and proteins for the MMTT. Blood samples will be drawn through the IV at regular intervals for 2 hours.

If you are asked to do both an MMTT and OGTT, they will need to be performed on separate days.

- **HbA1c Test**

This blood test measures a person's average blood glucose level for last 2-3 months before the test.

- **Blood Samples for Understanding Type 1 Diabetes**

Blood samples may be obtained to better understand how type 1 diabetes, progresses and to get ideas about new treatments in the future. While TrialNet is ongoing, these samples will be used only by TrialNet approved researchers. As such, we may be collecting blood samples for these studies at most of your visits. You will not routinely be provided with test results from these studies. We will discuss with you the type of tests to be done.

Most of the time the study will need about 1- 2 tablespoons of blood from adults. We will let you know about how much blood we need to take. We will not take more than is safe. For those under age 18, we will not take more than is safe for your age and weight.

Will I be given the results of the tests?

Yes, you will be offered the results of your OGTT, MMTT and HbA1c testing soon after each visit.

You may have the option of going to another study site for follow-up if it is more convenient for you. If so, your contact information will be shared with other TrialNet investigators to make arrangements for you to be followed at another study site.

What are the possible risks of taking part?
You could have discomfort and/or a bruise when you get your blood drawn. Once in a while, some people may faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and surrounding tissue or bleeding where the needle enters the skin. Some people may feel nauseous when they have the OGTT. The use of Boost during the MMTT has no known side effects, but you may not like the taste.

What are the possible benefits of taking part?
There is no guarantee that you will benefit from this study. During the study we will share with you information about your health and diabetes.

Will payment be available?
You will receive a small amount of money for each study visit as well as for minor travel and/or parking costs. If this research project results in a product that can be sold, you will not receive a share of money that is made.

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. More information on this is given in part 2

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in part 2.

PART 2

Will I have to stay in the study until the end?

You are free to stop being in this study at any time. Your current or future care or that of your family will not be any different if you decide not to be in this study or to stop being in this study at any time. You will be told of any new findings that may affect your being in this study.

As long as TrialNet continues, you can have your stored blood samples destroyed at any time if you wish. Once TrialNet is over your samples cannot be destroyed, since they can no longer be identified as belonging to you.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (PI: Prof Polly Bingley, Research nurse Harriet Castleden 0117 323 8736).If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. It is highly unlikely that anything will go wrong. If taking part in this research project harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?

Yes. Your consent to be in this study gives the TrialNet researchers permission to collect personal information about you and to use it for research purposes. Your consent also includes permission for the sponsor of this study (NIDDK), the Food and Drug Administration (FDA) and the Medicines for Health Research agency (MHRA) to review your records.

Personal information is information such as your name that directly identifies you. This personal information may be sent to another NHS site for data processing and will be kept in a database at the UK TrialNet Coordinating Centre at the University of Bristol. We may

share your personal information with other TrialNet study investigators to help you participate.

If you participate in this study, you will be given a unique study code number. It will identify the information and samples collected from you from study examinations and procedures. It will be sent to the central TrialNet Coordinating Center at the University of South Florida.

When TrialNet is completed, your data (but not your personal identifying information) will be moved to another location that will be under the supervision of the NIDDK. Once this happens, it will no longer be possible to link your code to your name or other personal identifying information.

A Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). This is intended to further protect the confidentiality of information that we obtain about you. By having a Certificate of Confidentiality, TrialNet researchers are not required to give information that can be used to identify you. For example, we cannot be forced to give information about you to insurance companies. Also, we cannot be forced to give information about you for any civil, criminal, administrative, or legislative proceedings whether at the federal, state or local level. However, the Certificate of Confidentiality does not prevent you from giving this information to others. Please understand that we will maintain the confidentiality of your research record. We cannot guarantee the confidentiality of test results provided to you if you wish to share them.

There are some rare exceptions to the protection offered by the Certificate of Confidentiality. TrialNet researchers are not prevented from telling about matters such as child abuse, certain infectious diseases, or threatened violence to yourself or others.

TrialNet researchers will consider your records private. Rarely, representatives of the United States Department of Health and Human Services (DHHS) or TrialNet may review or ask for a copy of your study records. If this happens, we will provide your records. Also, for auditing purposes, employees of the University of Bristol, North Bristol NHS Trust, University Hospitals NHS Trust or their agents could be allowed to see your study records to make sure that the study is being done properly.

The results of this study may be published for scientific purposes. By signing this form, you are agreeing to this. Your records and results will not be identified as belonging to you in any publication.

Who is funding the research?
The study is being organised by a number of institutions: it is sponsored by the National Institutes of Health (NIH), primarily the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Other support is from the Juvenile Diabetes Research Foundation and the American Diabetes Association. The study is being organised by the University of South Florida; in the UK the coordinating centre is the University of Bristol.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a research ethics committee, to protect your interests. This study has been reviewed and given a favourable opinion by the South West – Central Bristol Research Ethics committee.

Who can I ask from more information?
You are encouraged to ask any questions you may have about the study. In the event of a research related injury, you should contact the trial team immediately (Research Nurse Harriet Castleden phone 0117 323 8736). If you have any questions about your rights as a research subject, you may contact North Bristol Trust Research and Innovation at phone 0117 323 8605.

Will I be told if any new information arises?
You will be told of any new findings that may affect your being in this study.

Principal Investigator:
Prof Polly Bingley, Diabetes & Metabolism, Southmead Hospital, Bristol, BS10 5NB Tel: 0117 323 6233

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Long Term Investigative Follow-up in TrialNet (LIFT) (TN-16)
Consent form

Please read the Information sheet before you complete this form.

Name of Researcher: **Professor Polly Bingley**

Please **initial** all boxes

1. I have read and understood the information sheet (dated 13th May 2014, Version UK02) about the study or it was read to me. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the TrialNet Study Group, the University of Bristol, the regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to my contact details being sent to the TrialNet coordinating team at the University of Bristol for administrative purposes. These will not be passed on to any third party outside of the TrialNet study team and will be treated in confidence. ☐

6. I agree to take part in the above study. ☐

The following sections are choices you can make. Ticking the "no" box does not mean you cannot take part in the study:

Information about other research

I consent to the research team contacting me about other research for which I may be eligible.

YES ☐ **NO** ☐ **INITIALS** ☐

Storage of Samples in NIDDK Repository

When TrialNet is over, we intend to put any remaining samples into the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) repository for future studies related to type 1 diabetes and its complications. They will be stored there indefinitely without your name or any other identifying information on them. As such, once in the repository you will not be able to have them removed. Researchers must first get permission from the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) to use samples from the repository.

The following checkbox gives you the choice of allowing us to put any remaining blood samples in the NIDDK repository. Even if you decide not to have your remaining blood samples stored, you can still participate in this study.

Are you willing to allow us to put any remaining blood samples in the NIDDK repository?

YES ☐ **NO** ☐ **INITIALS** ☐

Signatures

Participant	
Print Name of participant:	
Signature of participant (age 12 or older)	
Date of participant's signature:	
Parent/guardian (if subject < age 18)	
Print Name of parent or guardian:	
Signature of parent or guardian:	
Date of parent/guardian signature:	
Consent obtained by:	
Print name of researcher:	
Signature of researcher:	
Date of researcher's signature:	