DIRECT: SCREENING EXERCISE for prediabetes glycaemic deterioration (Study WP2.1a)
Participant Information Sheet and Consent Form
<site name>

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We are writing to you to invite you to take part in screening for a research study. The study requires people with certain characteristics, so we would first like to confirm whether you are eligible for this study. The information below explains about the screening, and the study for which the screening is being done.

Before you decide whether or not you wish to take part in screening for the project, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with information about the screening and about the study itself. Please read it carefully, and feel free to ask any questions you may have and, if you want, discuss it further with your doctor, friends or family. We will do our best to provide further information and answer any questions you may ask for now or at a later date. You do not have to make an immediate decision. Agreeing to be screened for eligibility does not mean you have to take part in the project. You can decide this separately.

What is the purpose of this Research?
We know that some people are at a higher risk of developing diabetes than other people. We know some of the reasons why this is – for example, risk is increased in people who are overweight or who have a family history of diabetes. However, despite these known risks there is still a lot we don't know about why people get diabetes. We are aiming to identify biological markers that will help us predict whose blood sugar levels will worsen over time and whose blood sugar levels will remain stable. This in turn will help us develop the most effective ways of preventing and treating diabetes.

Who is conducting this research?
The research is being funded by the European Union, in conjunction with funding from some leading pharmaceutical companies. Collectively, this group of European researchers and scientists is called the DIRECT consortium and it is interested in learning about the risk factors for diabetes and how people with diabetes present or respond to treatment. The day-to-day organisation of the research in <region> is being co-ordinated by <local PI>. A number of centres are involved across Europe and Lund University is the co-ordinating centre. <insert site details> is the legal sponsor of the study (taking legal responsibility for it).

Why have I been asked to become involved?
You have been asked to consider screening for this research study because, according to measurements made on you in previous research studies, you do not have diabetes but may be at increased risk. Studying people like you in this "pre-diabetic" stage may provide new information on how diabetes develops and how to distinguish those who are likely to go on to develop the disease from those who will not. Importantly, many people with pre-diabetes remain at this stage for a long time and some will never develop the disease.

Therefore, we will ask you to undergo a series of new measurements (outlined below), which will help us determine whether you are still eligible for the DIRECT study; these screening measurements will be done by you, using a kit that we will mail to you. Once you have collected the relevant information, we will ask you to return this information and a spot of blood to us by mail or in person if it is convenient. This screening test is to identify what your risk factors are for

developing diabetes. You will be eligible for the full study if the results from the screening tests indicate that your blood glucose (sugar) levels are likely to increase substantial during the next few years. Importantly, although elevations in blood sugar levels are a risk marker for diabetes, it does necessarily mean you will develop the disease. Indeed, many people with elevated blood glucose levels remain healthy for many years.

What does the study involve?

Although the information collected on you previously indicates that you are eligible for this study, because of changes in your blood glucose levels, you may no longer be so. Therefore, we will ask you to undergo a series of new measurements (outlined below), which will help us determine whether you are still eligible for the DIRECT study; these screening measurements will be done by you, using a kit that we will mail to you. Once you have collected the relevant information, we will ask you to return this information and a spot of blood to us by mail or in person if it is convenient. This screening test is to identify what your risk factors are for developing diabetes. You will be eligible for the full study if the results from the screening tests indicate that your blood glucose (sugar) levels are likely to increase substantially during the next few years. Importantly, although elevations in blood sugar levels are a risk marker for diabetes, it does necessarily mean you will develop the disease. Indeed, many people with elevated blood glucose levels remain healthy for many years.

Whether or not you are eligible for the full study, we would like to keep your screening information in anonymised form as part of a larger population profile of blood glucose levels.

The screening involves:

- Measuring your height, weight, and hip, waist and thigh circumferences. A guide and tape measure will be provided to help you.
- Collecting a blood spot on a piece of blotting paper, which we will use to estimate your blood glucose levels and other blood markers related to diabetes. A kit will be provided.
- Completing a questionnaire about your medical history and any medication you take that we will ask you to complete.

If you are eligible to participate in the full study, we will give you further information about it in order for you to be able to decide. We will also send you additional questionnaires and a stool sample kit (with all information on how to use it), which you will be requested to complete for the first visit of the full study.

Will there be any risks?

The screening for the study does not involve any procedures with any significant risks.

Are there any direct benefits to those taking part?

In general there is no major direct benefit to you as a participant in this study. The main benefit is that through this research, we hope to better understand the causes of diabetes, which may lead to improved prevention and treatment of the disease.

What about confidentiality?

We regard the protection of your personal information (i.e., the security of any data we collect from you as part of this study) as being extremely important. We have special systems in place to make sure that once we obtain your consent and you have completed the study visits that we then separate your name, address and other information that might identify who you are from the rest of your data, which helps ensure third parties cannot link information about your health to your name, address or other information that identifies who you are.

When you have given consent to take part in the study we assign you a code known as a "study number". Your study number is then used in place of your name when keeping track of the remaining information or samples we collect from you. We will not write your name, address or health record number on any of your samples or on the forms that are used to collected information from you during the study. In this way, your study data and samples are anonymised. When the information and samples we collect from you are exchanged amongst scientists working within our study, your samples and data will be identified using your study code only and we will never pass on your name or address to scientists or third parties who are not directly involved in your clinical care, such as your GP. Your name will never appear in any report or publication that arises from this study.

Towards the end of the study we store the file and consent form containing your name, address, health record number and study number in a special locked database held separately from the rest of the information. This is never shared with anyone outside of the research team in <study site>. The only reason for safely storing this information is to allow information from your past and future health care record to be extracted and linked anonymously to the study data for the next 10 years. >delete if not appropriate for site

What will be done with the information collected about me?

The information we collect from you and the blood sample will be stored for the duration of the DIRECT project and used as part of this study to investigate why people get diabetes. The studies to be carried out will include measures of blood glucose (HbA1c) and measurements of other relevant biomarkers such as genotypes.

Who will have access to my anonymised data and samples and how will this be controlled?

This study is being conducted by a large group of European doctors and scientists at Universities and Hospitals as part of a consortium that includes a number of companies from the pharmaceutical industry. None of these groups will ever have access to your name, date of birth or address. Your anonymised data will be stored on secure computers at the research centre and at the central DIRECT data facility in Denmark. These data will be accessible by members of the consortium and by approved members of the scientific research community, but access to the data and your blood will require approval by a data access committee which will ensure that all use of the data and samples is for justified scientific research and that these data and samples are handled in a secure way that safegaurds your confidentiality. Your samples and data will only be used for research involving diabetes, its treatment and related conditions. Where necessary, permission will be sought from an ethics committee to use your samples or data for future studies into diabetes, its treatment and related conditions. We may also invite you to take part in future studies based on the results from the DIRECT study.

Where commercial companies conduct research or provide financial assistance to non-commercial researchers to do the research, they could require the commercial rights to benefits arising from the discoveries. To allow potential collaborators to proceed you are asked to waive any future claim to financial benefit through participation in the study. So for example, if a company discovered the basis of a new diabetes drug by using your blood sample (as one of thousands of blood samples), and went on to profit from this discovery, you would have no future claim on this profit.

Who has reviewed this study?

The <insert relevant ethics committee details here>, which has responsibility for scrutinising all proposals for medical research, has reviewed the proposal. It is a requirement that the research

records are made available to monitors from Lund University whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Could you choose not to take part?

Yes, of course. Participation in this study is entirely voluntary. If you chose not to participate, you wouldn't have to give a reason why and it would not affect any future medical care you may receive. It is in your and our best interests that you only participate in this study if this is something you freely decide to do.

Could you withdraw from the study?

Yes. You would be free to withdraw from the study at any time by contacting your local diabetes study team (contact details are at the end of this document). You would then carry on with your diabetes treatment as planned by your health care team. We would still store and utilise your samples and data collected up until that point unless you specifically ask us not to by formally withdrawing your consent. If you decided to withdraw your consent, we will destroy all of your samples held by us and from then on any anonymised data collected from you would not be included in the analyses we perform as part of this study. Importantly, if your anonymised data had already been included by researchers in an analysis from which results had been derived and reported, this could not be changed.

What about insurance companies?

Sometimes insurance companies ask people if they've ever had any genetic tests. However participation in this study does NOT constitute a "genetic test" as defined by insurance companies. The fact that you are taking part in this study will not affect your ability to get insurance. Data will never be released by us to a third party unless we are legally required to do so.

Will there be any further contact?

At the time of participation we will ask you to indicate if you are willing to be re-contacted by the study team in the future to be invited to participate in any ethically approved research related to this project.

Will my GP be informed that I am taking part in the study?

Yes, if you agree, your GP will receive a copy of the results that we provide for you.

What if I have a complaint?

If you are harmed as a result of taking part in this study, then compensation can be sought from the study sponsor. A copy of the guidelines is available on request. However, the sponsor will not compensate you where harm results from any procedure that is not in accordance with the study protocol. Under these circumstances, your right at law to claim compensation for harm where you can prove negligence is not affected.

Who should I talk to if I have any further questions or concerns?

If you have any questions regarding this study you can phone the study team.
<Contact details of study team>

Or if you wish to seek independent advice then please contact <details of local contact> who is a clinician with an interest in diabetes who is independent of the research team.

DIRECT
DIABETES RESEARCH ON PATIENT STRATIFICATION

PREDIABETES GLYCAEMIC DETERIORATION – SCREENING CONSENT FORM

NB. This form must be completed and signed by the research participant.

Please initial box

1.	I confirm that I have read and understood the above information section of this information sheet / consent form. 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 my consent at any time without giving any reason, without any medical care or legal rights being affected.	

I understand that:

3.	Information regarding any abnormal measurements will be communicated to my GP and/or hospital physician.	
4.	The information I provide and data about me will be stored for many years on secure electronic databases, which can be accessed by researchers who are members of the DIRECT consortium, and by member of the scientific research community. This information will not include my name, social security numbers or address or date of birth.	
5.	My blood spot sample and anonymised data may be used in future projects by other researchers collaborating with the DIRECT consortium, including commercial companies, into diabetes and related conditions including genetic studies on DNA.	
6.	I may be asked to return for future studies based on the findings of the present study.	

7. **I agree to take part in the above study**.

_____ Date _____
Participant Name (PRINT)

Signature_____ Date of Birth_____*

THANK YOU for agreeing to take part in this research

I confirm that the nature of the research, the required additional procedures and the voluntary nature of the study have been explained in understandable terms.

_____ _____
Name of person taking consent (PRINT) Date

Signature_____

*Your date of birth will only be used as a key when storing information relating your study ID (as in barcode above) to ensure it relates to you. Your date of birth will be encrypted and will not be accessible to view by anyone.

Participant Study ID_____

*** affix consent barcode here ***