DIRECT
DIABETES RESEARCH ON PATIENT STRATIFICATION

PREDIABETES GLYCAEMIC DETERIORATION – FULL STUDY CONSENT FORM (version 1.4)

NB. ***This form must be completed and signed by the research participant in the presence of someone with knowledge of the research designated by the Principal Investigator. This may be a doctor, nurse, clinical research assistant or other member of the research team, and this person must countersign the form as witness to the participant's signature***

Please *initial* box

1. I confirm that I have read and understood the information sheet dated **April 27 2012 (version 1.7)** for the above study. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.	
2. I confirm that I am aware that I will need to attend the hospital or clinical research facility on up to 6 occasions during the next 3 years.	
3. I confirm that I am aware that I will receive a body scan (MRI)	
4. I understand that my participation is voluntary and that I am free to withdraw my consent at any time without giving any reason and without my usual medical care or legal rights being affected.	
I understand that: 5. My GP will be informed that I am taking part in this research study Relevant information about my health can be accessed from my medical records by the research team during the study period.	
6. Apart from the standard clinical blood tests collected in this study, which will be made available to my health care team, my blood and urine will be anonymised and will be analysed and then stored for the duration of the DIRECT project.	
7. Information regarding any abnormal measurements (e.g. high blood pressure) and important findings on the MRI scan will be communicated to my GP and/or hospital physician	
8. The information I provide and data about me will be stored for many years on a secure electronic database, which can be accessed by researchers who are members of the DIRECT consortium and, where appropriate, by members of the scientific research community. This information will not include my name, social security numbers, address or date of birth.	
9. My blood and urine samples and anonymised data may be used in future projects by other researchers collaborating with the DIRECT consortium, including commercial companies, who are conducting research on diabetes and/or related conditions including genetic studies on DNA as described in the Information Sheet.	
10. I agree to researchers contacting me about future studies based on the findings of the present study.	
11. I understand that <insert site details>, as sponsor to this research, may require access to my medical records for study monitoring purposes only, thereby ensuring that the research is properly conducted and the interests of those taking part are adequately protected.	

12. I understand that I am allowing transfer and storage of my samples, including hereditary information such as DNA and RNA, for analysis in medical research on the assumption that it is free of any legal claim on my part and without expectation of personal financial gain.	

I agree to take part in the above study.

_____ _____

Participant's name (PRINT) Date

Participant's 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 to me 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 ***