DIRECT
DIABETES RESEARCH ON PATIENT STRATIFICATION

CONSENT FORM (Group A full study) (version 6)

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 who must countersign the form as witness to the participant's signature***

Patient Identification Number for this study: _____

Please *initial* box

1. I confirm that I have read and understood the information sheet dated **January 16, 2014 (version 6)** for the above study. I have had the opportunity to consider the information, 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 at least 3 occasions, and that if my diabetes responds very well or very poorly to the new injectable diabetes treatment I will be asked to attend for an additional 2 visits ☐
3. I confirm that I am aware that I will receive an MRI scan (body scan) ☐
4. 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. ☐
5. **I understand that:** ☐
   - My GP will be informed that I am taking part in this research study ☐
   - Information about my diabetes can be accessed from my health records by the research team during the two and a half year study period. ☐
   - Apart from the clinical blood tests to assess my diabetes control (HbA1c), which will be made available to my health care team, my blood and urine will be anonymised and stored indefinitely. ☐
   - My MRI images will be made available indefinitely on the NHS radiology database, which will allow doctors who are looking after me access to these images in future. ☐
   - Information regarding any abnormal measurements (e.g. Blood pressure) and important findings on the MRI scan will be communicated to my GP and/or hospital physician ☐
   - The information I provide and data about me will be stored indefinitely on secure electronic databases, which can be accessed by researchers who are members of the DIRECT consortium, which includes pharmaceutical companies, and by members of the scientific research community. This information will *not* include my name, NHS number or address. ☐
   - My past and future clinical /NHS record data may be linked to the study data in an anonymised way. ☐
   - My blood and urine samples and anonymised data may be used in future projects by other researchers, including commercial companies, into diabetes and related conditions including genetic studies on DNA as described in the Information Sheet. ☐

6. I understand that if, during the 6 month study period, I become unwell and lose the ability to consent, all identifiable data and blood samples will be withdrawn from the study, but any data and blood samples that have been anonymised (i.e. are not identifiable to the research team) will be continued to be used. ☐

7. I understand that the University of Dundee and NHS Tayside, as joint sponsors 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. ☐

8. I understand that I am allowing transfer and storage of a specimen of my samples including the hereditary information 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. ☐

OPTIONAL
The following is <u>optional</u> and you can take part in everything else without agreeing to these.

I agree/do not agree (**PLEASE CIRCLE)** to being contacted in the future by the study team to discuss possible participation in further research into diabetes and related conditions. I understand that this does not commit me in any way to taking part in further research. ☐

_____ _____
Participant Name (PRINT) Date

Signature_____

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 terms understandable to the patient.

_____ _____
Name of person taking consent (PRINT) Date

Signature_____