The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Liverpool Diabetic Eye Screening Programme (3rd Floor UCD)
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Prescot Street
Liverpool
L7 8XP

Centre Name:_____ Centre Number: _____

Patient Identification Number: E __ __ __ __ __

Individualised Screening for Diabetic Retinopathy (ISDR) Study: a Randomised Controlled Trial

If the patient is unable to read the form for any reason (e.g. visually impaired, pupils dilated) a delegated researcher **must** read the whole form to them before asking them to sign their agreement. **Tick box if read to patient.**

☐

		Please initial box
1.	I confirm that I have read and understand Patient Information Leaflet A dated 26.02.14 (Version 1.0) for the above study.	
2.	I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
3.	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.	
4.	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the ISDR study team, Clinical Trial Research Centre, regulatory authorities, sponsor 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.	
5.	I understand that my medical data (with name removed) will be collected for this study and may be used to develop new research and that data protection regulations will be observed.	
6.	I agree to medical personnel responsible for my welfare, being informed of my participation in the study.	
7.	I agree to take part in the above study.	

Please circle **Yes** or **No** to confirm if interpreter is required: **Yes / No**

I have interpreted to the parent or guardian the information above to the best of my ability and in a way that I believe he or she has understood.

_____ _____ _____

Name of Interpreter (print) *Date (dd-mm-yyyy)* *Signature*

_____ _____

Name of Participant (print name) Date (dd-mm-yyyy) Signature

_____ _____

Researcher (print name) Date (dd-mm-yyyy) Signature

When completed please provide 1 (original) copy to the participant, 1 (original) copy to be stored in the ISF and 1 copy to be stored in medical notes according to local practice.

Figure 1. Original version of the ISDR consent form, tested in SWAT.

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

To be filled in by the researcher:

Centre Name: | Centre Number:

Patient Identification Number: E

If the patient is unable to read the form (e.g. visually impaired, pupils dilated) a delegated researcher must read the whole form to them before asking them to sign their agreement. Tick box if read to patient. ☐

To be filled in by the participant:

Once you have read and understood each statement **please tick (✓) and initial** (see example below).

Agreement to take part in the ISDR study (for participants aged 16+)			
No.	Statement	Initial	Tick box (✓)
Example	*I have read and understand the Participant Information Booklet.*	AZ	☑
1	I have read and understand the Participant Information Leaflet A dated 03/11/2015 (Version 4.0) about the ISDR study.		☐
2	I have had the chance to think about the information, ask questions and had them answered to my satisfaction.		☐
3	I understand that taking part is up to me, and that I can drop out of the study at any time without giving a reason, without my medical care or legal rights being affected.		☐
4	I understand that sections of my medical notes and study information collected about me may be looked at, when they relate to the study. I give permission for the following people to look at my records: staff from the ISDR study team, Clinical Trial Research Centre, regulatory authorities, study sponsor or from the NHS Trust.		☐
5	I understand that medical information about me (with my name removed) will be collected for the study. It may be used to develop new research and that data protection regulations will be observed.		☐
6	I agree to my GP and other medical staff involved in my care, being told of my taking part in the study.		☐
7	I agree to take part in the ISDR study.		☐
Optional	I agree to being contacted in future about the ISDR study.		☐

Participant name (please print):		Today's date	DD- MM-YYYY
Signature:			

This section to be filled in by the researcher after the participant has signed:

Researcher (print name): | Date: DD-MM-YYYY | Signature:

When completed please provide 1 (original) copy to the patient, 1 (original) copy to be stored in the ISF and 1 copy to be stored in medical notes according to local practice.

Please tick Yes or No to confirm if an interpreter is required: ☐ Yes ☐ No

This section to be filled in by an interpreter:

I have interpreted the information above to the best of my ability and in a way that I believe the participant has understood.

Interpreter (print name): | Date: DD-MM-YYYY | Signature:

MRC START ISDR Consent form 4.0 - 03/11/2015

Figure 2. Revised version of the ISDR consent form, tested in SWAT.