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APPENDICES

INFORMATION SHEET

Project Title: Factors associated with diabetic retinopathy requiring treatment on fundal photography in participants of the Cape Town Diabetic Retinopathy Screening programme.

What is this study about?

This is a research project being conducted by Mr HG Alexander at the University of the Western Cape. We are inviting you to participate in this research project because you are diabetic patient receiving medical care at a community health centre within the circumscribed study area. The purpose of this research project is to ascertain if there is any notable differences amongst the characteristic of a diabetic patient who presents with treatment-requiring diabetic retinopathy and those who present with non-treatment-requiring diabetic retinopathy.

What will I be asked to do if I agree to participate?

You will be asked to undergo retinal camera imaging which will coincide with your diabetic visit at your attending clinic. Thereafter an interviewer will ask you some general information with regards to your overall health and well-being. The other relevant study information will be sourced from your clinical folder.

Would my participation in this study be kept confidential?

We will do our best to keep your personal information confidential. To help protect your confidentiality, a code will be assigned to each patient thus keeping your particulars confidential. The review of the folders will be conducted on-site with permission from the relevant facility manager.

What are the risks of this research?

There are no risks associated with participating in this research project beyond the usual care you receive at the clinic.

What are the benefits of this research?

The benefits to you is to have the back of your eye photographed and evaluated by a professional grader, and include the necessary follow up care. The study forms part of the

current diabetic retinal screening program conducted at your facility, and the information obtained will lead to future improvements.

Do I have to be in this research and may I stop participating at any time?

Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify

Is any assistance available if I am negatively affected by participating in this study?

If you feel that partaking in the study had a negative impact either socially, emotionally and/or physically then assistance will be provided from the relevant facility managers.

What if I have questions?

This research is being conducted by, Mr HG Alexander from the University of the Western Cape. If you have any questions about the research study itself, please contact myself at:

The Woodstock Hospital (Eye Clinic)

Mountain Road

Woodstock

7925

Tel: (021) 447 0007

Email: henry.george.alexander@gmail.com

Should you have any questions regarding this study and your rights as a research participant or if you wish to report any problems you have experienced related to the study, please contact:

Director:

Prof Helene Schneider

School of Public Health

University of the Western Cape

Private Bag X17

Bellville 7535

hschneider@uwc.ac.za

Dean of the Faculty of Community and Health Sciences:

Prof Jose Frantz

University of the Western Cape

Private Bag X17

Bellville 7535

chs-deansoffice@uwc.ac.za

UNIVERSITY of the WESTERN CAPE

OFFICE OF THE DEAN

DEPARTMENT OF RESEARCH DEVELOPMENT

08 June 2015

To Whom It May Concern

I hereby certify that the Senate Research Committee of the University of the Western Cape approved the methodology and ethics of the following research project by:
Mr HG Alexander (School of Public Health)

Research Project:	Factors associated with diabetic retinopathy requiring treatment based on fundal photography in participants of the Cape Town Retinal Screening Programme.
Registration no:	15/4/35

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Office
University of the Western Cape

FIRST NAME	SURNAME	GENDER
ID	AGE	CHC
TEL NO	ADDRESS	

Place Clinic Sticker here

OCULAR HISTORY		
	DIABETES TYPE OF TREATMENT	DIAB ETE
CO-MORBIDITIES	ORAL SUPPLEMENTS	
SMOKING NO YES ….NUMBER OF PACKS PER DAY		
ALCOHOL CONSUMPTION …… DRINKS PER WEEK		
DATE OF LAST FUNDUS PHOTOGRAPH	DRS ATTENDANCE HISTORY IN THE PAST FIVE YEARS	

CLINICAL MEASUREMENT			CLINICIAN:
HEIGHT	WIEGHT	BP	WASIT CIRCUMFERENCE
BLOOD GLUCOSE	TODAY	6 MONTH AVERAGE	ONE YEAR AGO
MOST RECENT HBA1C	PEDAL EXAM		

EYE EXAMINATION		CLINICIAN:
HABITUAL VISUAL ACUITY	R	L
PINHOLE VISUAL ACUITY	R	L
INTRA OCULAR PRESSURE	R	L
RED REFLEX PRESENT	R	L
PUPIL REFLEX	R	L

DIABETIC RETINOPATHY SCREEN-ING	RIGHT EYE	LEFT EYE GRAD	FOLLOW UP CARE	
NO DIABETIC RETINOPATHY			ANNUAL REVIEW	
MILD/ MODERATE DIABETIC RETINOPATHY			6 MONTHS REVIEW	
SEVERE DIABETIC RETINOPATHY			REFER TO OPTOMETRIST	
PROLIFERATIVE DIABETIC RETINOPAHTY			REFER FOR TREATMENT	
MACULAR INVOLVEMENT				

I ……. HEREBY DECLARE THAT THE NATURE OF THE STUDY WAS CLEARLY EXPLAINED TO ME, AND THAT I CONSENT TO PARTAKING IN THIS STUDY.