Appendix 1. The operating characteristics of NM UWF imaging to detect diabetic eye disease.

Four observational studies have compared NM UWF imaging to other diabetic eye screening procedures to detect diabetic retinopathy (DR) and diabetic macular edema (DME).[1-4] Important strengths in common to the four studies were masking of personnel who obtained and read the NM UWF images to the results of the other screening tests, and generally low rates of ungradable NM UWF images because of poor quality (9.8%,[1] 10.8%,[2] 5.6%,[3] 7%[4]).

**Diabetic Retinopathy**

Neubauer et al. compared NM UWF imaging as graded by 3 experienced retina specialists to dilated pupil slit lamp fundus exam by patients’ retina physicians in 51 consecutive patients (51 eyes) from an outpatient ophthalmology clinic.[1] The retina physicians graded DR severity using the International Clinical Diabetic Retinopathy (ICDR) Scale (no DR, mild non-proliferative DR [NPDR], moderate NPDR, severe NPDR, and proliferative DR [PDR]). They found moderate (defined by kappa 0.41 – 0.6) to substantial (kappa 0.61 – 0.80) agreement in DR grading between NM UWF imaging by each retina specialist (kappas 0.51, 0.68, 0.68) as compared to dilated fundus exam by the retina physicians. Moderate to substantial inter-observer agreement among the 3 retina specialists in grading DR was also seen (kappas 0.49, 0.66, 0.72). At a specificity of 100%, the sensitivity across the 3 retina specialists to detect moderate NPDR or worse using NM UWF images was 94%.

Wilson et al. compared NM UWF imaging to dual-field mydriatic retinal imaging and to dilated pupil fundus exam by slit lamp biomicroscopy by a consultant or trainee ophthalmologist.[2] A total of 380 patients with diabetes (759 eyes) were recruited from patients undergoing general eye screening and from patients referred to a diabetic retinopathy clinic. The Scottish Diabetic Retinopathy grading scheme (R0 to R6 with grades R3 and R4 indicating DR for which referral is advised) was used to grade the NM UWF images, dual-field photographs, and dilated pupil fundus exams. They found that NM UWF imaging showed substantial agreement (kappa 0.60) to detect R3/R4 disease as compared to dilated pupil fundus exams. The respective sensitivity and specificity of NM UWF imaging to detect R3/R4 disease relative to dilated pupil fundus exam was 69% (95% confidence limits [56%, 81%]) and 94% (91%, 97%). These results were not statistically significantly different from corresponding values based on comparison of dual-field retinal images to dilated pupil fundus exams (kappa 0.63, sensitivity 67% [55%, 80%], and specificity 95% [93%, 98%]).
Kernt et al. compared NM UWF imaging with an UWF scanning laser ophthalmoscope to 7-field stereoscopic colour fundus photography and to dilated pupil fundus exam with slit lamp biomicroscopy by two experienced retina specialists.[3] A total of 141 consecutive diabetes patients (212 eyes) from an outpatient ophthalmology clinic were assessed. As the reference standard, the 7-field fundus photographs were read by two trained independent graders with the graders determining DR severity according to the Early Treatment of Diabetic Retinopathy Study (ETDRS) scale across 9 steps (no retinopathy [ETDRS level 10] to high-risk PDR [ETDRS level 75]). Substantial agreement between the NM UWF imaging and 7-field stereoscopic photography was seen between the two graders (kappas 0.77, 0.79). For comparison of NM UWF imaging and clinical assessment by slit lamp biomicroscopy, the ETDRS scale was converted to a 5-part clinical scale (no DR, mild non-PDR, moderate NPR, severe NPR, and PDR). Excellent agreement between the NM UWF images and the clinical assessments was seen with an exact agreement of 95.8 % and agreement +/- 1 step of 100%.

Silva et al. compared NM UWF imaging providing 100° and 200° of coverage to 35 mm 7-field stereoscopic colour fundus photography and to dilated pupil fundus exam by a retina specialist in 103 diabetes patients (206 eyes) from an outpatient clinic.[4] As the reference standard, the 7-field photographs were read and graded in 200 eyes by a retina specialist according to the ETDRS protocol using a 7-step scale (no DR, mild NPDR, moderate NPDR, severe NPDR, very severe NPDR, PDR, and high-risk PDR). The perfect level of agreement and within 1-step level of agreement between UWF imaging and 7-field photography was 84% and 91%, respectively. In a total of 190 eyes having both gradable 7-field fundus photographs and NM UWF images, a substantial level of agreement (weighted kappa 0.85) was seen between the NM UWF images and the reference standard. For comparison of dilated fundus exam by a retina specialist to NM UWF images (n = 197 eyes), the perfect level agreement was 70%, within 1-step level of agreement 93%, and weighted kappa 0.77. The sensitivity (99%), specificity (100%), positive predictive (100%) and negative predictive values (92%) of NM UWF imaging for detecting no DR versus any DR as compared to 7-field fundus photography were also very high.

**Diabetic Macular Edema**

In Neubauer et al.[1] comparing NM UWF imaging read by 3 retina specialists to dilated pupil fundus exam by patients’ retina physicians, macular edema was graded on both procedures according to the ICDR severity scale (none, mild, moderate, or severe) and according to presence or absence of CSME.
Using the ICDR scale, fair levels of agreement were seen between NM UWF imaging as read by each retina specialist and dilated pupil fundoscopy (kappa values 0.20, 0.27, and 0.25). However, for the more important finding of CSME the NM UWF images showed good to excellent sensitivities (89 to 93%), specificities (72 to 89%), and positive (84 to 93%) and negative predictive values (83 to 89%) when compared to dilated pupil fundus exam.

In Wilson et al.[2] comparing NM UWF imaging to dual-field mydriatic retinal imaging and dilated pupil fundus exam by a consultant or trainee ophthalmologist, the investigators used the dilated pupil fundus exam as the practical reference standard and also included the Scottish DR grading scheme for diabetic maculopathy (M0 - none; M1 - exudate within 1 to 2 disc diameters from the fovea; and M2 – exudate or blot hemorrhage within 1 disc diameter of the fovea) where M2 is an indication for referral. A moderate level of agreement was seen between the NM UWF images and dilated pupil fundus exam for any level of macular edema (kappa 0.48). For macular edema needing referral, the NM UWF images showed good to excellent sensitivity (81%), specificity (91%), and negative predictive value (97%), but a lower positive predictive value (49%) likely in part because of the low prevalence (12%) of M2 disease on dilated pupil fundoscopy. In further analyses focusing on diabetic eye disease needing referral (R3/R4 and/or M2), they found that NM UWF imaging showed substantial agreement with dilated pupil fundus exams (kappa 0.67) with good sensitivity (84%) and specificity (90%). These results were not statistically significantly different from the corresponding values based on comparison of dual-field retinal images to dilated pupil fundus exams (kappa 0.70, sensitivity 83%, and specificity 91%).

In Kernt et al.[3] comparing NM UWF imaging to 7-field stereoscopic colour fundus photography and to dilated pupil slip lamp fundus exam by two experienced retina specialists, the presence of CSME on 7-field fundus photographs was graded by two expert readers according to the ETDRS classification. Agreement between the readers was higher for the NM UWF images than for 7-field photographs with respective exact agreements of 91% vs. 87.5%, and respective agreements within 1 step of 100% vs. 98.6%. For CSME, substantial levels of agreement were seen between NM UWF imaging and 7-field fundus photographs as read by the two experts (kappa values of 0.73 and 0.77).

In Silva et al.[4] comparing NM UWF imaging to 7-field fundus photography and to dilated pupil fundus exam by a retina specialist, the 7-field photographs were used to grade macular edema severity by the ETDRS protocol (none, DME, and CSME). For 156 eyes having both 7-field photographs and
NM UWF images gradable for macular edema, moderate to substantial levels of agreement were seen (kappa 0.60 and weighted kappa 0.66). The respective sensitivity, specificity, positive and negative predictive values of NM UWF images to detect CSME vs. no CSME relative to 7-field photography were 76%, 94%, 88%, and 87%. The corresponding values for detection of any DME including CSME vs. no DME were 73%, 94%, 88%, and 84%.

References


### Appendix 2. Participant Timeline

<table>
<thead>
<tr>
<th>TIME POINT</th>
<th>Enrolment</th>
<th>Allocation</th>
<th>Post-Allocation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before usual SJHC endocrinologist clinic visit (-t&lt;sub&gt;1&lt;/sub&gt;)</td>
<td>Eligibility screen X</td>
<td>At usual SJHC endocrinologist clinic visit (t&lt;sub&gt;0&lt;/sub&gt;)</td>
<td>Within 2 weeks of SJHC endocrinologist clinic visit (t&lt;sub&gt;0&lt;/sub&gt; + 2 weeks)</td>
</tr>
<tr>
<td></td>
<td>Informed Consent X</td>
<td></td>
<td>Within 12 months of SJHC endocrinologist clinic visit (t&lt;sub&gt;0&lt;/sub&gt; + 12 months)</td>
</tr>
<tr>
<td></td>
<td>Allocation X</td>
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</table>

#### ENROLMENT
- Eligibility screen
- Informed Consent
- Allocation

#### INTERVENTIONS
- NM UWF Screening
- Usual Screening
- OCT Screening

#### ASSESSMENTS
- Baseline Variables
- Outcome Variables

SJHC, St. Joseph’s Health Care; NM UWF, nonmydriatic ultrawidefield; OCT, optical coherence tomography
Appendix 3. Data Collection & Management

All data collection will be performed by dedicated study personnel (coordinator and assistant). Electronic case report forms have been created using REDCap, a secure web-based data management system. Baseline and follow-up data collected will be entered into the REDCap-based database which has been constructed including data quality rules to ensure accuracy. Outcome data will be transcribed electronically from the paper reports (NM UWF imaging reports, OCT reports, Usual Care Screening reports from participants’ eye care professionals) into REDCap. Only study team personnel will have access to the paper and electronic database records. All data collection and storage will adhere to Western University’s security and privacy policy in order to ensure confidentiality. The Principal Investigator will have access to the final trial dataset.

**Baseline Data** - After eligibility has been confirmed and informed consent has been obtained from participants by the study personnel, all participants will undergo a brief assessment by the study coordinator (history and review of medical chart) to assess important relevant demographic and clinical factors, including the stratifying factors. These data will be collected using a standard electronic case report form.

**Outcomes** - After randomization, all participants will have outcome data collected from within 12 months of randomization. For Usual Screening group participants, the outcome data will be transcribed from the written report of the usual eye care professional and for the On-Site Screening group participants, the NM UWF imaging (± OCT) results will be transcribed from the paper report forms from the study ophthalmologist (JG) and the usual care screening data transcribed from the written report of the usual eye care professional.

For all participants, data on other non-diabetes-related eye disease (i.e. glaucoma, cataracts) will also be collected. Additionally, information regarding changes (if any) in their smoking status, or to their medications for glycemic control, blood pressure control and lipid lowering, as well as follow-up A1C levels, lipid levels, and blood pressure from randomization to the time of their usual screening eye exam by their eye care professional will be collected via their SJHC endocrinologist’s chart and/or via telephone call to the participant. If they were seen again in the Diabetes Clinic by their SJHC endocrinologist in the interim, information on whether a fundoscopic exam was performed during that visit will be collected from the physician chart.
Appendix 4. Sample size considerations.

The trial will occur at St. Joseph’s Health Centre (SJHC) in London which is a tertiary care hospital affiliated with Western University. The Division of Endocrinology & Metabolism is sited on the 5th floor at SJHC and includes the offices and outpatient clinics of 11 adult endocrinologists involved in the care of ~4,000 active DM patients. The Division of Ophthalmology is sited on the 2nd floor at SJHC within the Ivey Eye Institute and includes 8 ophthalmologists who treat patients with diabetic eye disease. All patients with diabetes who meet inclusion criteria will be approached to participate at their usual routine clinical care visit.

<table>
<thead>
<tr>
<th>% Screened in Usual Screening Group</th>
<th>60%</th>
<th>65%</th>
<th>70%</th>
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<tbody>
<tr>
<td>AED Rate in On-Site Screening Group</td>
<td>8.5%</td>
<td>9.0%</td>
<td>9.5%</td>
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<tr>
<td>P_E</td>
<td>0.078</td>
<td>0.083</td>
<td>0.087</td>
</tr>
<tr>
<td>P_C</td>
<td>0.030</td>
<td>0.030</td>
<td>0.030</td>
</tr>
<tr>
<td>N/group</td>
<td>342</td>
<td>296</td>
<td>260</td>
</tr>
<tr>
<td>Total N including 10% loss-to-followup</td>
<td>760</td>
<td>658</td>
<td>578</td>
</tr>
</tbody>
</table>

\[ P_C = \text{the AED rate in participants randomised to the Usual Screening group who have a documented eye exam by an eye care professional within one year of entry} \]

\[ P_E = \text{the AED rate in participants randomised to the On-Site Screening group who are screened by NM UWF imaging and who have a readable image} \]
The sample size estimation is based on the primary outcome of AED as defined for the On-Site and Usual Screening groups. The above table shows that the main sample size determinants are the: a) rate of detection of AED in the Usual Screening group ($P_C$) where $P_C$ is, in turn, determined by the rate of screening and, among those screened, the rate of AED; and b) rate of detection of AED in the On-Site Screening group ($P_E$). With 740 randomised participants, the study will have 80% power to identify at least a 5% absolute increase in the rate of detection of AED among On-Site Screened versus Usual Screened participants. This absolute difference translates into a number-needed-to-screen by on-site NM UWF imaging of 20 to detect 1 additional person with AED relative to usual screening, and corresponds to a relative increase in rate of detection of AED by NM UWF imaging of 60%.

We have assumed a rate of detection of AED in the Usual Screening group ($P_C$) of 3.3%. For the screening rate in the Usual Screening group, we have assumed a rate of 65% based on: a) an Ontario study[1] that found screening adherence rates in diabetes patients of 57%, and b) the finding in our Pilot Study that 33% of diabetes patients had not had an eye exam by an eye care professional for at least a year. We have assumed that screening adherence in the Usual Screening group will be higher than that reported in the Ontario study[1] because of a “healthy volunteer” effect and also a “study effect” that occurs because we are encouraging participants to arrange an eye exam.

For the rate of AED in the Usual Screening group who have been screened, we have assumed that 5% will have AED. Studies elsewhere have found rates of diabetic eye disease that appear congruent to our definition of AED (eg., disease needing referral) of 4 – 5% using screening methods comparable to those endorsed by the CDA.[2-7] In our Pilot Study we found a comparable rate for AED (3.9%) in a review of 229 diabetes patients charts from a London optometry office but, because the majority of the participants in Clearsight will be drawn from patients who are referred to an endocrinologist, we have assumed the higher rate of 5%.

We have assumed a rate of detection of AED in the On-Site Screening group ($P_E$) of 8.3%. By design, the screening rate among On-site Screening participants will approach 100%. A small proportion of patients who undergo NM UWF imaging have unreadable images for patient-related or technical reasons. In our Pilot Study, 134/135 subjects had interpretable UWF images but lower rates (6 - 11%) are reported elsewhere.[8-11] We have therefore assumed that 92% of participants randomised to the On-Site Screening group will be both screened and will have readable images. For the rate of AED
among On-Site Screening participants who provide readable images, we have assumed a value of 9.0% which is consistent with the rate of 9.7% seen in our Pilot Study.

Other parameters incorporated into the table are: a) 10% of participants randomised to the Usual Screening group will be lost to followup as this means we will be unable to obtain records of participants undergoing eye exams by eye care professionals within 1 year of entry; b) 1:1 allocation to Usual and On-Site Screening groups; and c) the N per group is given by:

\[(Z_{\alpha} + Z_{\beta})^2 [P_E (1-P_E) + P_C (1-P_C)]/(P_E - P_C)^2\]  
where \(Z_{\alpha} = 1.96\) (two-tailed) and \(Z_{\beta} = 0.84\) (80% power)

References


Appendix 5. Statistical Analysis Plan

The statistical analysis will be supervised by the study biostatistician and will use SAS version 9.3 (SAS Institute Inc., Cary, NC).

Primary Analysis

Baseline characteristics of all randomised participants will be summarized using descriptive statistics including means and standard deviations (if normally distributed) or medians and interquartile range (if highly skewed distributions) for continuous variables, and percentages for dichotomous or categorical variables.

The primary analysis will use an intention-to-screen approach where attribution of the outcome of AED will be to the screening group (On-Site or Usual) to which participants were randomised. Data from all randomised participants will be included in the primary analysis with the exception of participants who are found, after randomization, to have undergone a screening exam by an eye care professional within 12 months of entry. (Data from these participants will be included in secondary analyses.) The primary analysis will assess the unadjusted proportions of AED between On-Site and Usual Screening groups by Pearson’s chi-square or Fisher’s exact test as appropriate. The comparison will test a superiority hypothesis in favour of On-Site Screening at a two-tailed significance level of 5%.

For participants with missing primary outcome data, sensitivity analyses that compare the proportions of AED between On-Site and Usual Screening groups based on imputing missing outcomes by “worst-case/best-care scenarios” will be done. The potential impact of baseline imbalances on AED rates between On-Site and Usual Screening groups will be assessed in logistic regression analysis that adjusts for baseline A1C level, previous treatment for diabetic eye disease, BP level, smoking status, fenofibrate treatment, age, and gender. Given that the definition for AED includes “re-examination in <12 months” which as a stand-alone criterion could potentially reflect practice patterns or other reasons aside from clinical need, a sensitivity analysis excluding this as an AED criterion in the Usual Screening group will also be performed.

For all analyses, including the secondary analyses described below, in which 95% confidence limits and p-values are generated, the estimates will not be adjusted for multiple comparisons and will be qualified by this proviso when they are reported.
Secondary Analyses

To assess secondary outcomes bearing on screening adherence, the proportions of participants who complete a screening exam as required by protocol (a documented eye exam by a non-study eye care professional within 12 months for Usual Screening participants and a NM UWF image for On-Site Screening participants) will be compared between groups using Pearson’s chi-square or Fisher’s exact test as appropriate. The proportions of participants who complete an eye exam by a non-study eye care professional within 12 months irrespective of screening group assignment will be similarly compared between the On-Site and Usual Screening groups.

To assess secondary outcomes bearing on DME, the proportions of participants with CSME as detected by the primary screening method, viz., NM UWF images (On-Site Screening) or an eye exam by a non-study eye care professional (Usual Screening) will be compared between groups using Pearson’s chi-square or Fisher’s exact test as appropriate. Additional comparisons will be done for: a) the proportion of participants with DME detected by NM UWF imaging plus OCT among On-Site Screening participants versus an eye exam by a non-study eye care among Usual Screening participants; and b) the proportion of participants with DME detected by NM UWF imaging alone versus NM UWF imaging plus OCT among On-Site Screening participants.

Further exploratory (hypothesis-generating) analyses will include, but will not be limited to, comparison of the proportions of detection of AED between the On-Site and Usual Screening participants within subgroups based on baseline characteristics (eg., A1C level, previous treatment for diabetic eye disease, smoking status, BP level, fenofibrate treatment, age, gender, duration of diabetes, and T1D vs. T2D). For continuous variables (A1C and BP level, age, and duration of diabetes) the cutpoints to define the subgroups will be chosen in advance and will not be based on data inspection.
**LETTER OF INFORMATION**

**CLEAR SIGHT: A Randomized Trial of Non-Mydriatic Ultra-Widefield Retinal Imaging to Screen for Diabetic Eye Disease**

**Study Investigators:**

<table>
<thead>
<tr>
<th>Role</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Selina Liu, MD MSc FRCPC</td>
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<td>St. Joseph’s Health Care London</td>
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<tr>
<td>Irene Hramiak, MD FRCPC</td>
<td>St. Joseph’s Health Care London</td>
</tr>
<tr>
<td>Jeffrey Mahon, MD MSc FRCPC</td>
<td>St. Joseph’s Health Care London</td>
</tr>
<tr>
<td>John Gonder, MD FRCSC</td>
<td>St. Joseph’s Health Care London</td>
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<tr>
<td>Neil Klar, PhD</td>
<td>Epidemiology &amp; Biostatistics</td>
</tr>
<tr>
<td></td>
<td>Western University</td>
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</table>

**Invitation to Participate:**

You are being invited to participate in **CLEAR SIGHT: A Randomized Trial of Non-Mydriatic Ultra-Widefield Retinal Imaging to Screen for Diabetic Eye Disease** because you have had a diagnosis of type 1 diabetes for at least 5 years or a diagnosis of type 2 diabetes for any duration and have not had a screening eye examination within the past 12 months.

**Purpose of the Letter:**

This letter will provide you with the information required for you to make an informed decision regarding participation in this research. You will also have the opportunity to discuss the study further with your usual Endocrinologist or your Diabetes Education Centre health professional and the study research team.

**Purpose of the Research Study:**

The purpose of this research study is to assess the effectiveness of using on-site eye photography on the same day as your Diabetes Clinic or Diabetes Education Centre visit to screen for diabetes-related eye disease (“diabetic retinopathy”). The photography to be used is a new type of technology (“non-mydriatic ultra-widefield retinal imaging”) that does not require dilation of the eyes (so no eye drops are needed), and is able to include a larger area of the back of your eye in the photograph. The camera used allows for a wider portion of the eye to be photographed. It is also relatively quick to perform, thus it is hoped that the results of this study may help improve the rates of screening and the rates of detection of eye disease from diabetes. Approximately 740 patients will take part in this study at St. Joseph’s Health Care London.
Eligibility:

All individuals who have had a diagnosis of Type 1 diabetes for at least 5 years or a diagnosis of Type 2 diabetes for any duration are eligible to participate if they have not had a screening eye exam for diabetes-related eye disease in the past 12 months.

Study Procedures:

If you agree to participate, it may require 0 or 1 extra visit to St. Joseph’s Hospital. You will be randomly assigned (like a flip of a coin) to 1 of 2 groups by a computer generated program:

(1) Usual Screening Group
(2) Camera Group

The Usual Screening Group will not have any photographs taken of their eyes, but as per usual standard of care, it will be recommended that they arrange their usual yearly eye exam with their eye care professional.

The Camera Group participants will have photographs of their eyes taken using a new camera (see image below) at the Ivey Eye Institute after their Diabetes Clinic or Diabetes Education Centre visit. This will take approximately 5-10 minutes. Taking the photographs involves sitting on a chair with your head supported on a chinrest, looking into the camera one eye at a time while focusing on a green light. The photographer may move the chinrest slightly up or down or to the side to centre your eye on the camera.

As well, if you are part of the Camera group, you will also be randomly assigned (like a flip of a coin) a second time to 1 of 2 groups by a computer generated program:

(a) Optical Coherence Tomography (OCT) Group
(b) No OCT Group
The OCT group will have a second set of photographs of the eyes taken with a different camera at the Ivey Eye Institute that checks for a different type of condition related to diabetes (“macular edema”). This may be done on the same day, and will take an additional 10-15 minutes, but may possibly be scheduled on a separate day. The “No OCT” group will not have this second set of photographs taken.

Neither camera require dilation of the eyes, so no eye drops are needed. Again, as per usual standard of care, it will also be recommended to all participants in this group that they arrange their usual yearly eye exam with their eye care professional.

In addition, if you agree to participate, we will ask that you sign a medical release of information form to communicate with your usual Endocrinologist and/or Family Physician and your usual eye care professional whom you see for your regularly scheduled screening for diabetic eye disease regarding your last eye exam date, your next usual screening eye exam results, and relevant diabetes history, medications, and bloodwork results (including glycated hemoglobin, lipid profile, and blood pressure values).

**Medical Chart Review:**
Your medical chart maintained by your usual Endocrinologist or the Diabetes Education Centre will be reviewed to collect information related to your diabetes history and any past medical history related to your eye health.
Possible Risks and Harms:
There are no known risks or harms associated with non-mydriatic ultra-widefield retinal imaging or optical coherence tomography. There is no discomfort associated with the imaging.

Possible Benefits:
There is no direct benefit to you from participating in the study, but information gathered may provide benefits to society as a whole, as it may lead to improved screening and detection of eye disease related to diabetes.

Compensation:
You will not be paid for participating in this study. However, you will be reimbursed for your parking expenses associated with a longer duration visit at St. Joseph’s Hospital today.

Voluntary Nature of Participation:
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time with no effect on your future medical care. You do not waive any of your legal rights by signing the consent form.

Confidentiality:
Your full name and date of birth will only be used as identifiers to request information about your screening eye examination results from your usual eye care professional and about your history of diabetes from your usual Endocrinologist/Family Physician. Otherwise, your name and full date of birth will be kept confidential and not used for any other reason. They will be recorded separately from the study data.

For the study data, you will be assigned a unique study identification number for data collection and recording. Data will be stored in an electronic database for future use. Only your unique study identification number, initials and year of birth will be stored, and as such that data will be anonymous. All data collected will remain confidential and accessible only by the research study team. If the results are published, your name will not be used. No information that discloses your identity will be released or published without your knowledge and permission unless required by law. The collected information will be securely stored at St. Joseph’s Health Care. While we will do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your initials and year of birth may allow someone to link the data and identify you.

Your study doctor will keep a separate list linking your identification number to your name. The files from this study will be kept for a period of 7 years after the study has been completed. All paper records will be stored in a locked file and/or office. All electronic records will be protected by a user password and only accessible by the research staff. Representatives of Western University Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. Representatives of the Lawson Quality Assurance (QA) Education Program may look at the study data for quality assurance purposes. You have the right to access your research records and to request corrections of any data that are wrong.
Contact:
If you require any further information regarding this research project or your participation in the study, you may contact:

Selina Liu, Principal Investigator
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St. Joseph’s Health Care
Telephone #:

Irene Hramiak
MD FRCPC Endocrinology & Metabolism
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John Gonder
MD FRCSC Ophthalmology
St. Joseph’s Health Care
Telephone #

If you have any questions about your rights as a research participant or the conduct of the study, you may contact:
Dr. David Hill, Scientific Director, Lawson Health Research Institute
Telephone#:

If you agree to participate, you will be given a copy of this letter of information and of the signed consent form.