Madam, Sir,

You have been contacted to participate in a scientific study. The aim of this study is to confirm the performance of intraocular implant for cataract surgery, which is already on the European market. This implant provides better visual acuity from afar, intermediate, and up close, once the cataract is removed. The advantage of this implant over conventional implants is to limit the wearing of glasses for everyday life, and to minimize halos and glare compared to multifocal implants.
Before you agree to participate in this study it is important that you clearly read and understand the explanation below about the procedures envisage during this study.

The following information describes the purpose, procedures, benefits, discomfort, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time.

Before you give your consent for your participation in this follow-up, it is important that you read the following information. You will then be asked to sign the informed consent form and keep a copy.

This study is organized by SAV-IOL SA; it is carried out in accordance with Swiss laws in force and in accordance with internationally recognised principles. This study was approved by the Cantonal Commission (VD) of Ethics in Human Research.

Your participation in this study is voluntary and isbased on understanding the information below.

1. Objectives of the study

The purpose of this study is to evaluate the efficacy and long-term safety of the Lucidis intraocular implant - Instant Focus©.

2. General information about the study

This study takes place in a single centre in Lausanne. Patients are included based on the presence of a cataract that interferes with visual acuity and requires surgery. Up to 120 patients are expected to be included in this study.

If you decide to participate in the study, the completion of cataract surgery will be done according to the classic procedure, with the installation of an intraocular implant Lucidis - Instant Focus©.

Your participation in this study will last 1 year during which several consultations will be scheduled:

- at the beginning of the study: entry into the study and preoperative visit (maximum 14 days before surgery)
- the day of surgery
- the day after surgery (0 to 3 days after surgery)
- 1 week after surgery (7 to 10 days after surgery)
- 1 month after surgery (30 to 45 days after surgery)
- 6 months after surgery (180 to 195 days after surgery)
- 1 year after surgery (360 to 390 days after surgery).

During these consultations, you will be examined and will need to stay approximately 15 minutes more per consultation to ensure the time required to collect the data, the additional duration of the visits will not be charged.

The data will be collected at each visit by your ophthalmologist. The acts carried out will not result in any additional costs for you or your insurance. Additional trips to follow-up visits at 6 months and 1 year can be refunded against proof of an invoice by Jules Gonin Hospital according to the conditions listed below:

- Return journey from home to Jules Gonin Hospital
  - Car: 70 cts. / km
  - Train: actual costs in 2nd class
  - Taxis: Effective costs of up to CHF 50 per trip
  - Medical car: expenses not covered reimbursed.
  - Ambulance: not reimbursed.

You will not receive compensation for your participation in this study.

In the case of bilateral surgery, the data will be collected first for the first eye operated, then for the second eye. Follow-up visits after each operation can be combined if they meet the specified deadlines.

The next table summarizes the data collected at each visit.

Data collected	Screening the study	**Pre-operative visit** (D-Day - 14 to -1)	**Surgery** (D-Day)	Follow-up **Day 1** (J0 to 3)	Follow-up at **1 Week** (J7à10) Follow-up at **1 Month** (J30 to 45) *Follow-up at **6 Months** (J180 to 195)[2]* ***1-year** follow-up (J360 to 390)[2]*
Informed consent	X				
Demographics (age/sex)	X				
Inclusion/exclusion criteria under consideration	X				
Eye/eyes candidate for the operation	X				
Slit lamp examination		X		X[1]	X
Cataract history		X			
Contrast sensitivity In Photopic condition In Mesopic condition		X		X[1]	X
Uncorrected visual acuity - Close-up distance In Photopic condition In Mesopic condition		X		X[1]	X
Uncorrected visual acuity - Intermediate Distance In Photopic condition In Mesopic condition		X		X[1]	X
Uncorrected visual acuity - Distance In Photopic condition In Mesopic condition		X		X[1]	X
Best Corrected Visual Acuity - Far Distance In Photopic condition In Mesopic condition		X		X[1]	X
Defocus Curve In Photopic condition In Mesopic condition		X		X[1]	X
Abberometry		X		X[1]	X
Operated eye			X		
Information about the implanted lens			X		
General information about the transaction			X		
Side effects during the operation			X		
Post-operative side effects				X	X
Post-operative interview				X	X
Changes in medication since the beginning of the study				X	X

Only for the first 40 patients [1:] Optional

2: Additional study-related visits

3. Benefits of participating in the study

There is no benefit for you to participate in this study since a similar or identical lens will be implanted.

The benefits of Lucidis - Instant Focus© are:

- Improved visual acuity at all distances (near, intermediate or far) compared to a monofocal implant
- Reduce or eliminate the use of glasses for all distances (near, intermediate or far) compared to a monofocal implant
- Improved sensitivity to contrast
- Reduce or remove unwanted visual symptoms (light halos, ghost images or other artifacts)

4. Risks and inconveniences of participating in the study

The study we propose to participate in is a follow-up over 1 year after implantation of an intraocular lens Lucidis - Instant Focus©.

There is no risk associated with this observational study because the lucidis - Instant Focus© intraocular lens is a medical device approved under the European Medical Devices Directive and is already available on the market in Switzerland and Europe. Other implants exist on the market and an implantation of the lens Lucidis - Instant Focus© is also possible outside the study.

The following complications are related to the surgery itself.

Common: discomfort, red eyes, watery eyes, dry eyes (the first few weeks after surgery).

More rarely: rupture of the posterior capsule, inflammatory reaction of the anterior chamber, leakage at the incision, development of subcapsular veil, macular edema.

Exceptional in nature: decompensation of corneal endothelium, intraocular infection (endophthalmites), retinal detachment, retrobulbar hemorrhage, impaired vision including total loss of vision (blindness).

Specifically for multifocal implants (Lucidis - Instant Focus © does not belong to the category of multifocal implants): halo vision, glare, photophobia, decreased visual acuity due to decentralization of the implant.

5. Voluntary nature of participation

You can withdraw from this study at any time for any reason and without consequences, even after you initially gave your consent. No longer participating will not affect your relationship with your ophthalmologist.

If you choose not to participate in this study, you will not similar or identical lens will be implanted and diagnostic tests and standard treatments will be provided to you by your ophthalmologist.
At any time, you have the right to access the collected data and correct any information through your ophthalmologist.
If the study is withdrawn, the data collected and coded will be analyzed.
Your personal data will not be disclosed.

6. Privacy

For the purposes of the study, we will have to register your personal and medical data. However, we will code this data. Encoding means that all the data that identifies you (for examples the name, date of birth, etc.) is replaced by a code, so that people who don't know this code can't link that data to you. Within the Jules Gonin Eye Hospital Institution, the data can be accessed by authorized and clearly designated persons, including in an unencrypted form. The code remains permanently within the Jules Gonin Eye Hospital Institution.

During its course, the study may be inspected. These can be carried out by the authorities who took over its initial control and authorized it, but also be mandated by the promoter. Their goal is to ensure that the rules are followed and that your safety is not threatened. The investigating physician may need to disclose your personal and medical data for the purposes of these inspections. In case of damage, an insurance representative may also be required to consult your data. However, this can only concern the elements absolutely necessary for the investigation of the case.

Your name cannot be published in any of the reports or publications that would result from this study.

You will be informed by your ophthalmologist/study physician of any discoveries that will be of importance to you.

7. Data experimentation

Your data will be kept for 15 years after the end of the study, in accordance with applicable law.

You can withdraw from the study at any time if you wish. However, we will analyze the medical data we have collectedso far, so as not to compromise the value of the study as a whole.

8. Responsibility

No complications have been observed in practice with this type of implant, other than the already known risks for routine cataract surgery. In case of damages related to your participation in the study, full compensation will be granted to you. For this study you are covered by the liability insurance of SAV-IOL SA, covering any damage. Your ophthalmologist/study physician will assist you in the process in the event of an incident.

Obligations of subjects participating in clinical follow-up:

Your participation in the study does not imply any special obligation on your part, other than to inform your ophthalmologist of all your medical history, allergies and treatments that you are currently taking within the limits of your knowledge. In the event of an emergency or hospitalization, your ophthalmologist should be informed either directly byyour family or by a loved one. In addition, you will need to inform any other doctor you may have to refer to.

9. People to contact

This clinical follow-up will be conducted under the direction of Dr. Kate Hashemi, Associate Physician, Unity cornea and refractive surgery. In the event of an emergency, uncertainty or unexpected or adverse event occurring during or after the study, you can contact: Dr. Kate Hashemi, Tel. 41 21 626 8 740, e-mail: kattayoon.hashemi@fa2.ch.

Don't hesitate to ask questions if some aspects seem unclear or if you want clarification.

Clinical study title:	PMCF Lucidis - Instant Focus©	
Promoter:	SAV-IOL SA, Route des Falaises 74, 2000 Neuchâtel	
Location:	Jules Gonin Eye Hospital / Blind Asylum Foundation Avenue de France 15, Lausanne, Switzerland	
Doctor-investigator	Name and surname:	Dr Kate Hashemi
Patient	Name and surname: Date of birth: Sex:	.... Male - Female

- I state that I have been informed by the investigating physician of this study, orally and in writing, of the objectives and conduct of the study as well as the presumed effects, benefits, potential disadvantages and potential risks. I had enough time to make my decision.

- I received satisfactory answers to the questions I asked in relation to my participation in the study. I keep the information sheet and receive a copy of my written consent statement.

- I know that my personal data will only be transmitted in coded form to external institutions for research purposes. I accept that the competent specialists of the study proponent, the authorities and the Ethics Commission may consult my raw data for data analysis and control purposes, provided that their confidentiality is strictly assured.

- I am volunteering in this clinical study. I may, at any time and without having to provide any justification, revoke my consent to participate in this study, without suffering any inconvenience in my subsequent medical follow-up.

- I am aware that the requirements mentioned in the patient information will have to be met during the study. The investigating physician may interrupt my participation in the clinical study at any time in the interest of my health. For my part, I undertake to inform the investigating physician of any treatment prescribed by another doctor as well as the taking of medication (prescribed or purchased by myself).

- I am also committed to informing theinvestigating physician of any unexpected phenomena that may occur during this study and to comply with the recommendations of this physician.

Patient signatures:	
I agree to participate in clinical research related to the implantation of an intraocular lens at extended focus distance	•

Location, date:	Signature:

Doctor-investigator's certificate:	
I attest by my signature to have explained to this patient(e) the nature, importance and scope of the study. I declare that I meet all obligations in relation to this clinical study. If I were to be aware, at any time during the completion of the study, of information that could affect the patient's consent to participate in the study, I undertake to inform him or her immediately.	
Location, date:	
Doctor-investigator's signature:	