**PARTICIPANT INFORMATION SHEET AND CONSENT FORM**

Version 1.0, Dated 6th July 2015

**Study Number: PEGA-2802**

***Section A: The Research Project***

1. Title: One-Day Clinical Evaluation of a PEG Cast-Moulded Soft Contact Lens.
2. Purpose of the Study

The purpose of this study is to compare the clinical performance of two different soft contact lenses.

Both contact lenses used in the study have been CE marked, which means that they conform to the appropriate European Union regulations. This study will provide information to the sponsor to help them make decisions regarding development of future contact lenses.

1. Invitation to Participate

You are being invited to take part in a research study involving wearing one lens type in one eye, and the other lens type in the other eye over a period of six to eight hours over the course of one day.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask the investigator if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

1. Who is organising the research and what is the source of funding?

Ocutec Ltd is sponsoring the study.

1. What will happen to the results of the study?

The results of the study will be used by the sponsor to make decisions about manufacture of contact lenses. The results of the study may be published in a journal or sent to the appropriate health authorities in any country in which the product may be marketed, but your name will not appear in these documents.

1. Who do I contact if I would like further information?

If you have any questions about the study, or in the event of a study related injury, please contact one of the investigators listed on the Consent Form (Farnham 01252 718719).

For questions about your rights and safety as a research participant, you may also contact INVOLVE Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD. **Telephone: 023 8065 1088** **Fax:** **023 8065 2885 Email:** **admin@invo.org.uk****.**

***Section B: Your Participation in the Research Project***

1. Why have I been invited to take part?

The participants involved in this study will be selected because they are 18 years old or older, have healthy eyes and are current soft contact lens wearers. You will not be included in this study if you are pregnant or breast-feeding, however there are no anticipated risks to the unborn child of using these products. Also you will not be included if contact lens wear should be avoided by the presence of any of the following conditions:

* Unacceptable (microscopic) findings such as swelling, small vessels growing into the cornea i.e. the front part of the eye, small defects in the front surface of the eye, bumps on the inside upper eye lid, redness, white blood cells and other eye problems.
* You have a systemic disease which affects the health of the eyes.
* You are taking any medications which may have an effect on your eyes.
* You have severe insufficiency of lacrimal secretion (moderate to severe dry eyes) that would affect the wearing of contact lenses.
* You have persistent and severe corneal or conjunctival staining of the eye using fluorescein dye.
* You have ever had refractive surgery.
* You are participating in any other type of eye related clinical or research study.

Approximately 20 participants are expected to be enrolled at one investigative site in the UK, the Visioncare Research Clinic, Farnham.

1. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this Participant Information Sheet and a copy of the Consent Form to keep. You will be asked to sign the consent form once you have had the opportunity to read all the instructions and information provided and received satisfactory answers to any questions you may have. If you decide to take part you are still free to withdraw at any time and without giving a reason.

There are other available contact lens care products currently on the market whose risks and benefits are likely to be similar to the study products.

1. How do I withdraw from the study?

Your participation in this study is completely voluntary. You are free to decide not to take part or withdraw at any time and without giving a reason. Your decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. To withdraw, complete the last section of the Consent Form and return to the investigator.

1. What will happen to me if I take part?

At the first visit, after you have signed the consent form, eye measurements will be taken to ensure that you are eligible to take part in the study. These will include questions about your general health and contact lens history, vision check, measures of your eyes and a check of the health of your eyes. If suitable, a pair of soft contact lenses will be put in your eyes. You will have one lens type in one eye, and the other lens type in the other eye. You will be asked to wear these lenses for between six to eight hours. The power of the lenses will not necessarily match the prescription of your eyes, therefore you may be provided with spectacles to correct your vision. The decision as to what lens type will be put in what eye will be assigned at random (i.e. by a computer). Neither you nor the investigator will know which lens type is in which eye. It is important you wear only the study lenses during the course of the study and do not use any sorts of eye drops (including rewetting drops).

There will be two follow-up assessments, 30 minutes after the lenses have been inserted into your eyes and then again after six to eight hours. At these assessments, study measurements will be taken including vision, lens fitting, and subjective responses (i.e. how you feel about wearing contact lenses). Your eyes will be examined and will recorded by video or photograph at each of the assessments, although the images will be of your eyes only and you will not be identifiable from the photographs taken.

The initial assessments will take approximately one hour and the two follow-up assessments will take approximately 35 minutes.

You must remove your lenses immediately if a problem occurs. You must contact the investigator conducting this study immediately if you notice any pain, discomfort, redness, blurring of vision, or any other possible adverse reaction.

1. What are the possible risks of taking part?

Problems with contact lenses or lens care products can result in injury to the eye. Due to the nature and duration of the study the risks of participating in the study are extremely low.

Complications of contact lens wear can include light sensitivity, swelling of the cornea (the front part of the eye), red eye, corneal vascularisation (small blood vessels growing into the cornea) and, in extreme cases, corneal infection. Smoking increases the risk of corneal infection. If a complication should occur during the study your eye may be photographed, a longer appointment may be necessary, you may be referred for medical treatment and/or what has occurred may be reported to the sponsor. You may be required to wear spectacles for a period of time.

The investigator will inform you in a timely manner of any new information about the contact
lenses used in this study which might develop during the course of this research and which might influence your wanting to participate in this study. The investigator, according to his or her judgement, may also stop the study or withdraw you from study at any time if it is considered to be in your best interests. If any problems or questions arise during the study, you should contact the investigator.

1. What if something goes wrong?

Should you require medical treatment as a result of your participation in this study, it will be provided to you free of charge by the sponsor, but neither the investigator nor the sponsor will automatically provide any other compensation to you. You will not lose any legal rights by participating in this study.

1. What do I have to do?

You will be required to follow the instructions in this Participant Information Sheet and the directions given to you by the investigator. You are required to follow the assessment schedule. If you experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems, you must remove your contact lenses and contact the study investigator immediately. Assessments will be made available to you at your request, or if the investigator thinks it is in your best interests.

1. What will happen to any information or data collected during the study?

As described above, the results of the study will be used by the sponsor to make decisions about how they manufacture contact lens care products. If the results of the study are published, your name will not appear in these documents.

1. What are the possible benefits of taking part?

There are no expected clinical benefits for you in taking part in this study.

The results obtained from this study may or may not benefit you directly but will have a positive impact for contact lens wearers in general as the information will help contact lens manufacturers develop improved contact lens care systems.

1. Will I receive any payment for my participation in the study?

If you are successfully enrolled in the study, as compensation for your time, travel and participation, you will receive £20 per scheduled assessment (i.e. £60 in total if you complete all three assessments as part of the visit). There is no cost to you for study procedures. The contact lenses will be provided free of charge for the duration of the study.

1. Is there anything else I can do for my eyesight?

You should continue to go to your regular eye care practitioner even if you join this study. You do not have to be in this study to get help for your eyesight. The study investigator can talk to you about other things you can do for eyesight and there potential risks and benefits. Some other things you can do are:

* wear spectacles
* use approved soft or hard contact lenses
* get laser or other refractive surgery
* have no vision correction

You can talk to your primary eye care provider about your options.

1. Will my information be kept confidential?

All information that is collected about you during the course of the study will be kept strictly confidential.

To ensure the accuracy of data, the sponsor or sponsor’s representative (i.e. Visioncare Research Ltd), the health authorities, or the Research Ethics Committee (an independent committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants) may inspect the study records. Inspection of the files will be conducted by appropriately qualified staff, and your identity will only be traceable at the site of the study. Any information about you, which leaves the clinic, will have your name removed so that you cannot be recognised from it. It will not be possible to identify you from any photograph we take of your eyes. By signing the consent form you are authorising the access to the information collected as described above.

1. Who has reviewed the study?

This research study has been reviewed and given ethics clearance by the Aston University Research Ethics Committee.

YOU WILL BE GIVEN THIS SHEET TO KEEP

**STATEMENT OF INFORMED CONSENT FORM**

Version 1.0, Dated 6th July 2015

**Study Number: PEGA-2802**

Title: One-Day Clinical Evaluation of a PEG Cast-Moulded Soft Contact Lens

Investigators: Lee Hall BSc (Hons), PhD, MCOptom, FBCLA
Graeme Young MPhil PhD FCOptom DCLP

 Please initial box

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| --- | --- |
| 1. I agree to take part in the above research. I have read the Participant Information Sheet, which is attached to this form. I understand what my role will be in this research, and all my questions have been answered to my satisfaction. | ⬜ |
| 2. I understand that I am free to withdraw from the research at any time, for any reason and without prejudice.  | ⬜ |
| 3. I have been informed that the confidentiality of the information I provide will be safeguarded. | ⬜ |
| 4. I am free to ask any questions at any time before and during the study. | ⬜ |
| 5. I will be provided with a copy of this form, the Participant Information Sheet and the Participant Instruction Sheet.Data Protection Act 1998: I agree to Visioncare processing personal data, which I have supplied. I agree the processing of such data for any purposes connected with the Research Project as outlined to me. I further agree to Visioncare processing personal data about me described as sensitive data within the meaning of the Data Protection Act 1998. | ⬜ |

Name of Participant Date Signature

Investigator/Person explaining consent Date Signature

Participant ID number: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

YOU WILL BE GIVEN A COPY OF THIS FORM TO KEEP

If you wish to withdraw from the research, please complete below and return to the investigators named above.

⬜ I WISH TO WITHDRAW FROM THIS STUDY

Signed: Date: