PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title:	**ONE-DAY CLINICAL EVALUATION OF A PEG CAST-MOULDED SOFT CONTACT LENS**
Protocol #:	**PEGA-2804**
Study Investigator:	_____
Address:	VisionCare Research, Craven House, West St, Farnham, GU9 7EN
Telephone Number:	01252 718719
After Office Hours:	07887 564320

INVITATION

You are being invited to take part in a research study that involves wearing soft contact lenses for eight hours. This form describes the study in order to help you decide if you want to participate. Before you decide to take part 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, and ask the study investigator or study staff about anything in this form that you have questions about or do not understand. Do not sign this form unless you are satisfied with the answers to your questions and decide that you want to be part of this study. You may consult with your family, friends or regular optician (if different) before deciding to participate if you would like to.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to compare the subjective performance of two contact lenses worn on a daily disposable basis. Both types of contact lens have been CE marked which means they are approved for use in the UK.

Up to 30 people who require correction to their eyesight and who are aged 18 years or older will try these approved contact lenses. This is called a "research study."

You require sight correction (contact lenses). The study investigator wants to know if it is okay to give you the approved soft contact lenses to try. You can say yes or no. You can ask the study investigator or study staff questions before you decide if you want to be in the study.

WHO IS PAYING FOR THIS STUDY?

A major contact lens manufacturer, Ocutec Ltd, is the sponsor of the study, and is paying for this study to happen. Ocutec Ltd is also paying the study investigator to do this study.

DO I HAVE TO BE IN THIS STUDY?

No, you do not have to be in the study if you don't want to. Your participation in this study is voluntary**.**

You can change your mind at any time. If you say “yes” now, you can say “no” and stop later. There will be no penalty to you, and you won’t lose any benefits that you are entitled to aside from being in the study. Your regular eye care at this study centre will not change if you decide to say “no.”

The study investigator or sponsor can withdraw you from the study at any time, even if you want to continue to be in the study. This could happen if:

- The study investigator believes it is best for you to stop being in the study
- You do not follow the study instructions.

- The sponsor stops the study for any reason.

If you want to stop being in the study, tell the study investigator or a member of the study staff and return any unused study contact lenses. If you stop being in the study early, the study investigator or study staff may ask you some questions about being in the study. They may also ask you to have some more tests to ensure your withdrawal from the study happens safely.

HOW LONG WILL I BE IN THE STUDY?

The study is designed to be approximately eight hours long. You will be asked to visit the study investigator's practice twice during the eight hours.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

You do not have to pay for study contact lenses, study visits, and tests that have to be done for the study. To find out more about costs, you can ask the investigator conducting the study.

While you are participating in the study, you still need to get regular care for your eyes. You (and/or your health care provider) will still have to cover the costs of your regular eye care that are not a part of this study.

HOW DO I KNOW IF I CAN BE IN THE STUDY?

Participants who are in this study will need to have healthy eyes, except for the need to correct their eyesight. You will not be included in this study if you are pregnant or breastfeeding; however there are no anticipated risks to the unborn child of wearing these lenses.

To be in this study all of the following should apply to you:

- You are greater than or equal to 18 years of age
- You are an adapted current soft contact lens wearers (i.e. you should have worn your current brand of contact lens for more than 1 month)
- You have the required prescription for the study (the study investigator will review this with you)
- You have read and signed this informed consent document
- You are willing to comply with the wear schedule
- You are willing to comply with the study visit schedule

You should not be in this study if any of the following apply to you (the study investigator will review this with you):

- You have any systemic disease affecting ocular health.
- You are taking any systemic or topical medications that will, in the investigator's opinion, affect ocular physiology or contact lens performance.
- You have severe insufficiency of lacrimal secretion (moderate to severe dry eyes) that would affect the wearing of contact lenses.
- You have an active corneal (i.e. the front part of the eye) infection, injury inflammation or abnormality
- You have had surgery to the front part of your eye.
- You are currently (to the best of your knowledge) pregnant, planning a pregnancy or lactating.
- You are participating in a concurrent clinical trial or have done in the last 14 days

WHAT WILL HAPPEN DURING THIS STUDY?

You will wear two different types of contact lenses during the study. Both types are currently CE marked (i.e. approved for use in the European Union) and we wish to evaluate how the lenses

perform in comparison to each other. If you normally use rewetting drops when you wear contact lenses you will need to stop using them for the duration of the study.

What happens when I come for study visits?

Before you can start the study, the study investigator or study staff will talk to you about the study. Then you have to sign this form before the study investigator or study staff can enrol you into the study.

Initial Assessments

If you decide to be in this study and the study investigator says you can be in the study, you will have an examination of the front part of your eyes and will be asked questions about your general health and contact lens history.

You will receive a new set of contact lenses to wear for eight hours. You should wear the study contact lenses as the study investigator has instructed you to wear them. You must not sleep in your contact lenses.

You will wear one of the lens types in one eye and the other lens type in the other eye. This is called contralateral wear. The eye to which each lens is dispensed to you will be decided by chance (like flipping a coin). When you have been enrolled on the study, a pre-prepared randomisation scheme will determine which eye receives which lens.

Once you have been assigned your new lenses you will again have an examination of the front part of your eyes and the study lenses and asked questions about your comfort and vision with these new lenses.

If you have any problems using the study contact lenses or problems with your eyes during the study, you should stop using the study contact lenses immediately and follow all the instructions on the Participant Instruction Guide. This is a separate document that will be given to you if you are given contact lenses to wear. You may need to come in for a later unscheduled visit to check on any problems you are having.

The study assessments do not take the place of your regular periodic eye examinations.

Follow-up Assessments

At the initial assessment you will be dispensed new contact lenses to wear for eight hours. Over the course of the next eight hours you will have follow-up assessments completed after approximately 30 minutes and 8 hours of wear. The first visit will include all assessments up to, and including, assessments after 30 minutes of wear. You will then be asked to return to the study investigator's practice again approximately seven and a half hours later (after eight hours total lens wear has elapsed) for your second visit, during which your eyes will be assessed again to determine how the lenses have performed.

You must not wear any other contact lenses during the study period. Depending on your contact lens prescription, you may be required to wear spectacles in addition to the study lenses to ensure that your vision is fully corrected. If this is required, you will be supplied with a set of spectacles to wear for the duration of the study. These will be provided to you free of charge. If you do not wish to wear the study contact lenses for any reason, you should wear your own spectacles.

The measurements taken throughout this study will be no different to those that should be conducted at a normal contact lens check-up visit. These will include for example, vision assessments, lens fitting, observation of the tear film (this is a film of tears that covers the eye and contact lens, the investigator will look at the tear film over the lens in each eye under magnification and assess the quality), and you will also be asked how you feel about wearing the study contact lenses. Your eyes

will also be examined after removal of the contact lenses. The assessments will take place over a total period of approximately 8 hours.

Study assessments are important in order to collect data about the study materials and to ensure continued ocular health. You must remove your lenses immediately if a problem occurs and follow all the instructions on the Participant Instruction Sheet. The study visits do not replace your regular periodic eye examinations, which you should carry on attending.

WHAT WILL HAPPEN WHEN THE STUDY IS OVER?

You should talk to the study investigator about your options for correcting your eyesight after the study is over.

IS THERE ANYTHING I NEED TO DO WHILE I AM IN THE STUDY?

While you are in the study, you must:

- Follow the instructions you are given.
- Come to the study centre for your visit with the study investigator.
- Tell the study investigator or study staff about any changes in your health.
- Tell the study investigator or study staff if you want to stop being in the study at any time.

ARE ANY OF THE STUDY TESTS PART OF MY REGULAR MEDICAL CARE?

Some of the study procedures might be performed as part of your regular medical care even if you do not take part in this research study. The study investigator or a member of the study staff can answer any questions you may have about the procedures that are not part of your regular medical care.

POSSIBLE RISKS OR DISCOMFORTS RELATED TO THE STUDY

WHAT CAN HAPPEN IF I USE THE STUDY CONTACT LENSES?

As the study lens is CE-marked and you are already a successful contact lens wearer, the risks to you from participating in this study are very low. All contact lens wear or lens care products, however, can carry a risk of serious injury to the eye. You should take particular care to follow the instructions given to you by the investigator, especially if the study involves a different lens care regime to your normal one.

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. Corneal infection may rarely cause a permanent reduction, or even loss, of vision. 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 company. You may be required to wear spectacles for a period of time.

The investigator will inform you of any new information about these lenses 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 at any time.

If you experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or have any concerns about your ocular health, remove your lenses immediately and speak to the investigator of the study.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I DO THIS RESEARCH STUDY?

There is always the possibility that during the study, new side effects or problems with the study lenses happen to you or other participants, which have not been seen before. The safety and

wellbeing of study participants is of paramount importance and the study sponsor has a duty to inform the investigator of any new information that is discovered during the study about the safety of the lenses. If the study investigator learns any new information about the study contact lenses while you are in the study, and it is the kind of information that might change your mind about continuing in the study, the study investigator or study staff will tell you about it.

ARE THERE RISKS TO ME IF I AM PREGNANT DURING THE STUDY?

Wearing contact lenses during pregnancy does not pose any health risks to either the mother or the foetus. Pregnancy, however, can change the nature of tears and affect contact lens comfort. Therefore, if you are pregnant, you will not be allowed to take part in the study.

WILL BEING IN THIS STUDY HELP ME?

The study contact lenses are designed to correct your eyesight while you are wearing them, but there is no guarantee that this study will help you. Your eyesight might not be corrected by the study contact lenses or might get worse while you are in this study. Information from this study may help researchers come up with new treatments to help others in the future.

WILL I GET PAID?

There is no cost to you for study procedures. You will not have to pay for study assessments or study contact lenses. The contact lenses will be provided free of charge for the duration of the study. As compensation for your time, travel and participation, you will receive a total compensation of £60 based on the successful completion of the study. You will not be reimbursed for travel expenses, other than described above. If you do not complete the entire study you will be reimbursed for the scheduled visits that you did complete at £30 per visit.

IS THERE ANYTHING ELSE I CAN DO FOR MY EYESIGHT?

You should continue to go to your regular optician even if you join this study.

You do not have to be in this study to get help for your eyesight. The study investigator will talk to you about other things you can do for eyesight. 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.

CAN I TALK TO OTHERS ABOUT THE STUDY CONTACT LENSES?

During the study, the study sponsor may share technical, economic, or business information about the study contact lenses with you. By agreeing to participate in this study, you agree not to share information about the study contact lenses with anyone outside the study without first obtaining written permission from the study sponsor. To ask questions about this, talk to the study investigator or study staff.

WHAT IF I GET HURT OR SICK WHILE I AM IN THE STUDY?

If you get hurt or sick while you are in this study, and the study investigator and the study sponsor reasonably determine your illness or injury to be a direct result of the study, medical treatment will be provided free of charge by the sponsor. If you have not followed the study investigator's instructions about the study, the sponsor may not pay these expenses.

The sponsor has made arrangements for insurance and/or indemnity to meet the potential legal liability of the sponsor arising from the study. You will not lose any legal rights by participating in this study.

To ask questions about this, talk to the study investigator or study staff.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions about the study please contact the investigator at any time using the telephone numbers on page 1 of this form.

Once the final study report has been completed, the investigator will be sent a summary of the results. If you wish to know the results of the study, the investigator will be able to make this summary available to you and you may take a copy of this summary if you wish.

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

WILL INFORMATION ABOUT ME BEING IN THIS STUDY BE USED AND SHARED?

This section explains how personal health information collected about you for the study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. The purpose of collecting this information is to allow the study staff and the study investigator to conduct the study, to evaluate the study contact lenses, and to analyse the study results. **Only your ophthalmic records may be reviewed by responsible individuals from the sponsor company, Visioncare Research Ltd or from regulatory authorities. At no point will your NHS medical records be reviewed.**

You may decide not to give permission for the release of your personal health information for the study. In that case, you will not be able to participate in the study. This is because the study staff and/or the study investigator will not be able to collect the information needed to evaluate the study contact lenses.

The study investigator may share your personal health information with the ethics committee that oversees the research and with the study sponsor, including people who work with the study sponsor. The people who work with the study sponsor may include data monitoring committees, contract research organizations, and consultants who have contracts with the company to do the study and review the study results.

Your optometric records, which include your name, may be inspected at the study investigator's office by the study sponsor and/or people who work with the study sponsor and by regulatory authorities, or by the Independent Ethics Committee overseeing this study. These reviews are done to check on the quality of the study, to check the information collected in this study, to check how the study is conducted, to monitor participants' safety, or for other uses allowed by law. Inspection of the files will be conducted by an appropriately qualified person, and your identity will only be traceable at the site of the study and will otherwise be kept fully confidential. Any information about you which leaves the clinic will have your name removed so that you cannot be recognised from it, however, you may cancel your permission at any time by writing to the study staff and/or the study investigator at the address listed on page 1 of this form.

The results of the study may be published in a medical book or journal or presented at meetings for educational purposes. Neither your name nor any other personal health information that specifically identifies you will be used in those materials or presentations. It is possible that the study investigator may want to photograph or videotape you or your eyes as part of the study. Your identity will not be shared without your permission if films, videotapes, or photographs are used for educational purposes or if photographs are used in medical or scientific books, magazines, or journals.

You have the right to see and copy your personal health information related to the study. You may also ask the study investigator to correct any study-related information about you that is wrong. You may have to wait until the end of the study to see your study records so that the study can be organized properly.

If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the study investigator at the address listed on page 1 of this form.

If you cancel your permission after you have started in the study, the study staff and the study investigator will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study investigator will not be able to collect the information needed to evaluate the study contact lenses.

You will be given a copy of this Participant Information Sheet and signed Consent Form to keep.

CONSENT FORM

Version 1, dated 24th January 2017

Study Title: One-Day Clinical Evaluation Of A PEG Cast-Moulded Soft Contact Lens

Please **initial** box

1. I confirm that I have read and understand all seven pages of the information sheet (Version 1, Dated 24th January 2017) for the above study and have had the opportunity to ask questions. Any questions I had were answered to my satisfaction.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my future care or legal rights being affected.	☐
3 I agree that photographs may be taken of my eyes, if needed, if there are any problems with my eyes.	☐
4. I understand that sections of any of my eye clinic notes and research data may be looked at by responsible individuals from the sponsor company, Visioncare Research or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my optical records for the period of this research project.	☐
5. Data Protection Act 1998: I agree to the sponsor company or Visioncare Research Ltd processing my personal data, which I have supplied, and I understand that my anonymised data will be sent to the sponsor company in the Scotland as a result. I agree to the processing of such data for any purposes connected with the research study as outlined to me. I further agree to the sponsor company or Visioncare Research Ltd processing personal data about me described as sensitive data within the meaning of the Data Protection Act 1998.	☐
6. I agree to take part in the above study.	☐

_____	_____	_____
Name of Participant	Date	Signature

I attest that I discussed this study with the above-named participant. This person had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

_____	_____	_____
Name of person taking consent	Date	Signature

_____	_____	_____
Name of Investigator	Date	Signature

OR ☐ N/A If Investigator is person explaining consent

Participant Identification Number for this trial: ____ / ____ / ____