Photospectra Health Sciences Inc.

CONSENT FORM:

Photobiomodulation Treatment for Dry AMD

Please review this document carefully, initialing each page once you have read it and sign and date the last page. If a family member has reviewed this document with you, please have them sign along side your signature on the final page. Please take your time and feel free to ask any questions before you consent to proceed with your treatment. Please ensure that you have discussed any questions with our medically trained staff.

This information and consent form describes the treatment. It may contain words you do not understand. If you have any questions, or do not understand anything in this form, please ask the doctor to explain. All of this information is part of your informed consent process and is provided to help you make the best decision for yourself and your eyes. The information contained in this document is not intended to frighten you or dissuade you from proceeding with your treatment, but merely to highlight any real or even possible risks associated so that you can be fully and properly informed.

BACKGROUND:

Age Related Macular Degeneration (AMD) is a progressive disease of the retina (the part of the eye that detects visual signals and transmits then to the brain).
AMD is the leading cause of loss of vision in people over 65 yrs.
There are two categories of AMD: the Dry or non-exudative form that accounts for 80 to 90% of all AMD cases and the Wet or exudative form that accounts for 10 to 20%.
This treatment is for Dry AMD.

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The exact cause of AMD is not known but there is evidence to suggest that several factors are involved. These include lack of blood flow to the retina through the small blood vessels; build up of waste products from retinal cells and inflammatory effects. There is currently no cure for AMD. There are several new and effective treatments for Wet AMD, however there are no proven treatments that are effective for Dry AMD.

Photobiomodulation is the application of specific wavelengths of light to the eye. The light source is Light Emitting Diodes (LED) which are very low powered and do not cause any heat damage to the eye. This is NOT a laser device. Light can produce many beneficial effects on cells and has been shown in previous preclinical studies to have a protective and regenerative effect on retinal cells.

There has been a recent clinical paper from Germany that used a very low powered laser through the globe (side part of eyeball) to irradiate the retina with light. A laser was used in this case in order to penetrate through the eye structures to reach the retina.

In this treatment a non-laser LED low powered light source will be used to shine light directly through the front of the eye to the retina. The German study showed significantly improved eyesight as measured on a standard eye chart in greater than 95% of eyes and this improvement was maintained for 3 – 36 months after treatment.

There were no adverse effects.

The Toronto and Oak Ridge study of Photobiomodulation in Dry AMD (TORPA) on which this treatment protocol is based has shown statistically significant improvement in vision and contrast sensitivity. Results were presented at the Association of Research and Vision in Ophthalmology (ARVO) 2012. There was one minor adverse event noted.

The results have been published in the Proceedings of the 9th World Association for Laser Therapy Congress (WALT) 2012.

Further results from the “off label” use of PBM in AMD patients has been presented at ARVO 2016, Euretina 2016 and has been

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published in ACTA Ophthalmologica – a high impact international peer reviewed ophthalmology journal.

PURPOSE:
The purpose of this treatment is to improve the function of the retinal cells affected by Dry AMD. The two LED devices used in this study seem to work by regenerating cells and protecting cells from further damage from AMD. The devices are approved by Health Canada and the FDA for clinical use but have not been used previously, except in the TORPA clinical trial, on the eye. The clinical indications are reduction of periorbital wrinkles, radiation dermatitis, acute and chronic pain (musculoskeletal).

TREATMENT INVOLVEMENT:
This treatment involves 9 visits to the clinic over 3 weeks.
The treatment visits will be 3 times a week for 3 weeks and each visit will take approximately 10 minutes. There is no special preparation needed prior to the treatment.
For each eye treated you will receive two light treatments, one with a red light that will be held by trained staff over your closed eye for approximately 80 seconds. The other light is a yellow light that will be held over both eyes for approximately 35 seconds. Any eye not undergoing treatment will be covered during the treatment.

CONTRAINDICATIONS:
To be eligible for the treatment you must have been diagnosed with dry AMD by an eye care professional and have no eye or general medical health problems that are contraindicated.
Because one of the devices emits a pulsed light ***no patients with a history of epilepsy or being treated for epilepsy should undertake the treatment.***

MEDICATIONS:
All the medications you usually take should be continued during this treatment.

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RISKS:

There have been many patients involved in previous studies of Photobiomodulation (PBM) for many different medical conditions including dermatitis and anti aging, stroke, musculoskeletal pain (many commercial clinics treat patients for arthritis, fibromyalgia and chronic injuries). There have been no significant adverse events reported.

There were no adverse events reported in a recent German study of 193 patients who were treated for macular degeneration. (Ivandic study).

There were no adverse events reported in the recent Acta Ophthalmologica paper.

There are no known teratogenic or carcinogenic effects.

There are no expected interactions with any medications with this treatment.

There may be possible unknown side effects that could occur.

There is a theoretical risk of increasing Vascular Endothelial Growth Factor (VEGF) expression with some wavelengths and power settings of PBM. This has been shown in retinal pigment epithelial cell cultures (Laboratory testing). In the TORPA study and with this treatment regime we have chosen light parameters to minimize this risk and reduce the expression of VEGF. Increased VEGF may increase the risk of retinal bleeding and is seen in wet AMD. Actively Wet AMD eyes will not be enrolled in this treatment. In the Ivandic study Wet AMD patients were treated with PBM and showed improvement in leaking and bleeding from the retina.

If any new safety information becomes available that may affect your decision to undergo this treatment you will be promptly informed.

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LIMITATIONS OF PBM:

AMD is a progressive disease. It is important to be aware from the outset that while recent studies have shown promising results, there are no long-term studies that have been published to help you and your doctors understand the potential benefits and risks for the use of PBM as it may relate to the long-term progression of macular degeneration. There are no guarantees or definitive evidence demonstrating that this treatment is beneficial or will reverse the long-term effects of the disease.

Initial results from clinical studies in Canada and Germany suggest that PBM may stabilize visual acuity and even improve vision in people with macular degeneration for most of the patients treated during the study period and for some time thereafter. Further analysis of the ongoing off label data collection has shown both functional and anatomical benefits. Although most patients have demonstrated improved vision in these studies, it must be emphasized that it is currently not possible to predict ahead of time which patients may achieve improvements in their visual acuity and vision, since patients' responses to treatment vary widely from one individual to another.

FEES PAYABLE:

To ensure patient candidacy, and maximize quality and safety, there are certain eye examinations and testing that must be completed by patients who wish to undergo PBM treatment. These tests are unlikely to be reimbursable by many health plans, the patient must pay directly. At present, provincial health insurance does not cover the procedure, although we recommend you speak with your accountant with regards to whether part or all of the fees are considered income tax deductible for you.

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BENEFITS:

No direct benefit is guaranteed to you from receiving the treatment. Your condition may or may not improve, or possibly even worsen. You may benefit from the monitoring that is part of the treatment protocol. The information gained from this treatment may help the development of better ways to treat other patients with Dry AMD.

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CONSENT

I have been given enough time to read this form and to ask questions. All of my questions, if any, have been answered to my satisfaction. I freely volunteer to take part in this treatment. By signing this form, I am not giving up my legal rights or releasing the doctor or Photospectra Health Sciences Inc from their legal and professional obligations. I have been offered a copy of this form to take home with me.

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Patient Name (printed) Signature

Date

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Witness Name (printed) Signature

Date

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Name of person administering consent (printed) Signature

Date

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