Salus IRB

18 January 2018

Thomas T. Henderson, MD
Attn: Valerie Gatavaski, COA
Eye Clinic of Austin
3410 Far West Boulevard, Suite 140
Austin, TX 78731

Re: GUARDiON Health Sciences, Inc., Protocol number 1

Dear Dr. Henderson:

The Protocol Version 2 dated 27 DEC 2017, and revisions to the Informed Consent Document (ICD) were approved using the expedited review procedure on 17 January 2018, as reflected on the attached document.

Due to the nature of the modifications, the reviewer has determined that reconsenting is required. Investigators must consider enrollment at their site as of the approval date listed and ensure any participants enrolled are reconsented at the next study visit.

If you have questions, or if we can provide further assistance, please contact our office at (512) 380-1244 or at salus@salusirb.com.

Sincerely,

Trina Anderson

Trina Anderson, CCRP, CIP
Quality Systems Manager

Salus IRB

MODIFICATIONS TO PREVIOUSLY APPROVED RESEARCH

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #: 1**

A. INVESTIGATOR AND STUDY INFORMATION:

1.	Name of Person Completing Form:	**Thomas T. Henderson, MD**
2.	Phone Number of Person Completing Form:	**512-427-1100**
3.	Email of Person Completing Form:	**thenderson@eyeclinic2020.com** **vgatavaski@eyeclinicof austin.com**
4.	☒ Investigator Name: **Thomas Henderson, MD** OR ☐ All Investigators currently approved (multi-site studies)	

B. REQUEST FOR REVIEW/APPROVAL (Check all that apply):

☒ Protocol Amendment/Revision **version and date:** Version 2 dated 27Dec2017 (TR 17Jan18)
- Include a detailed summary of changes/marked copy of protocol amendment
- Include copy of final protocol amendment or revised protocol

Do the changes to the protocol require modifications to the approved ICD? ☐ *No* ☒ *Yes*
If yes, please indicate below and include the requested modifications at this time.
If no, please attach a rationale for modifications not being necessary.

☐ Administrative/Clarification Letter **version and date:**

☐ Planned Protocol Deviations - a prospective, intentional deviation from the IRB-approved protocol (for further details on the reporting these events, see the Reporting Guidelines for Unanticipated Problems, Deviations and Other Safety Information):
- Describe the planned protocol deviation:
- Describe how the deviation is not consistent with the approved protocol:
- Provide the rationale for the planned deviation:
- Provide written documentation of the Sponsor's approval of this deviation
- If this change necessitates modifications to the ICD or addendum ICD, please indicate below and include the requested modifications at this time.

☐ Investigator's Brochure/Product Information (ex. package insert, device manual, etc.) **version and date:**
Do the changes to the IB or Product Information require modifications to the approved ICD? ☒ *No* ☐ *Yes*
If yes, please indicate below and include the requested modifications at this time.
If no, please attach a rationale for modifications not being necessary.
- Include a detailed summary of changes
- Include copy of revised Investigator's Brochure/Product Information

☒ Informed consent document (ICD) revisions
- Include a copy of the most current IRB-approved ICD indicating changes (tracked changes [contact our office for the Microsoft Word version] or handwritten changes are acceptable for minor revisions)

☐ New additional informed consent document/addendum
Please note: Please remove all formatting such as shading, text boxes, comments or hidden text from the ICDs before submitting to Salus IRB. ICDs submitted with such formatting may cause a delay in the review of this request and may result in additional administrative fees.

Salus IRB

MODIFICATIONS TO PREVIOUSLY APPROVED RESEARCH

SPONSOR: GUARDiON HEALTH SCIENCES **PROTOCOL #: 1**

☐ Recruitment and Study Material

Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file.

☐ New material ☐ Revised material

Identify which items and the quantity being submitted.

☐ Proposed printed advertisement, #
☐ Script of proposed video recording, #
☐ Participant screening tool, #
☐ Survey instrument(s), #
☐ Participant education material, #
☐ Other (describe): #
☐ Proposed web site content, #
☐ Script of proposed audio recording, #
☐ Participant Diaries, #
☐ Questionnaire(s), #

☐ Request for Salus IRB to Translate Study Documents:

- What documents would you like translated?
  - ☐ Consent Forms
  - ☐ Recruitment Material
  - ☐ Study Materials
- What language would you like them translated into? Language:
- Do you require a quote before proceeding with the translation? ☐ Yes ☐ No
- Do you require back-translation? ☐ Yes ☐ No

☐ Translated Documents:

- Please ensure the following is attached to this request;
  - ☐ Affidavit or Certification of accuracy from the translator
  - ☐ A copy of the English document translated. This must be the most current IRB-approved version.
  - ☐ A copy of the translated document. For consent forms, ensure the document is in an electronic Microsoft Word file.

☐ Other items requiring review (describe):

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #: 1**

THE FOLLOWING SECTIONS ARE FOR SALUS IRB USE ONLY

C. REVIEW AND DETERMINATION:

Type of Review:

☐ Deferred for Full Board Review – Reviewer Signature: _____

☐ Reviewed Only (Identify items):
- ☐ Investigator's Brochure/Product Information
- ☐ Study Material
- ☐ Other

☒ Approved
- ☒ Protocol Amendment/Revision
- ☐ Administrative/Clarification Letter
- ☐ Planned Protocol Deviations
- ☒ Revised ICD
- ☐ New ICD or Addendum
- ☐ Recruitment/Study Material
- ☐ Request for Salus IRB to Translate Study Documents
- ☐ Translated Documents
- ☐ Other

☐ Approved as modified (Identify items):
- ☐ Revised ICD
- ☐ New ICD or Addendum
- ☐ Recruitment/Study Material
- ☐ Other

EXPEDITED REVIEWER STATEMENT AND SIGNATURE:

The proposed modification(s) involves no more than minimal risk and represents minor changes in previously approved research during the period for which approval was granted and meets the criteria in accordance with 21 CFR 56.110 and/or 45 CFR 46.110. A minor modification means that the change does not change the risks of the research or affect the design of the research and all added procedures involve no more than minimal risk and that all added procedures fall into categories (1)-(7) of research that can be reviewed using the expedited procedure.

If the ICD is modified:

Is re-consenting required?
- ☐ No
- ☒ Yes, at the next study visit

☒ *My review of this item represents that I have no conflicting interests with the Sponsor, Investigator, or Protocol.*

Printed name of Reviewer (Chair or Designee): Mumtaz Ahmed, MD

Signature of Reviewer (Chair or Designee): Mumtaz Ahmed Date: 1/17/18

APPROVED BY SALUS IRB: 17 JANUARY 2018

AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT DOCUMENT

Sponsor:	GUARDiON HEALTH SCIENCES, Inc.
City and State:	San Diego, California
Protocol Number and Title:	1, Version 2: Controlled Study of the Effect of a Medical Food Containing All Three Carotenoids and Essential Cofactors Compared to AREDS2 on Early Macular Degeneration
Study Doctor:	Thomas T. Henderson, MD
Address of Study Site:	Eye Clinic of Austin 3410 Far West Blvd, Suite 140 Austin, TX 78731
24-Hour Telephone Number:	512-427-1100

INTRODUCTION

You are being invited to take part in a medical research study. Before you decide to take part in this study, you should read this document. This document, called an informed consent document, explains the study. Please ask as many questions as needed so that you can decide if you want to be in the study.

To be in this research study, you cannot already be in another medical research study.

You must be honest and complete in providing your medical history. Giving false, incomplete, or misleading information about your medical history, including past and present drug use, could have very serious health consequences.

The study doctor is being paid by the Sponsor to conduct this research study.

PURPOSE OF THE STUDY

The purpose of this study is to compare the effect of treatment with Lumega Z®, (a medical food containing lutein, zeaxanthin and meso-zeaxanthin, as well as other components) with treatment with AREDS2. AREDS 2 is a nutrient formula used for age-related vision loss that is available over the counter and marketed by Bausch & Lomb as PreserVision® AREDS 2. Lumega Z is different than PreserVision AREDS 2 in that it is available only by prescription and contains additional vitamins, antioxidants, and micronutrients.

APPROVED BY SALUS IRB: 17 JANUARY 2018

Patients with early signs of age-related vision loss (defined for this study as having yellow deposits in the retina and no or mild abnormality of dark adaptation) that take one of the two treatments (PreserVision AREDS 2 or Lumega Z) will be compared with those with normal dark adaptation and with the other treatment group.

WHAT WILL HAPPEN DURING THE STUDY

Each potential patient will undergo a screening test called AdaptDx to identify patients with normal dark adaptation and those with abnormal adaptation. AdaptDx is a machine used to test dark adaptation that involves looking into a dark field and recognizing when a light appears. All patients will receive the same exams at baseline, three months and six months (for details see listing below).

Those who are confirmed as normal dark adaptation will receive no treatment because they do not need this treatment. Those who are confirmed with a few drusen on Visucam photography and mild dark adaptation difficulty (less than or equal to 10 minutes on the AdaptDx) will receive one of two treatments below for 6 months:

- Lumega Z, a medical food, containing all 3 macular pigments, 10 mg lutein, 15 mg meso-zeaxanthin, 3mg zeaxanthin as well as essential cofactors and other antioxidants
- PreserVision AREDS 2 containing 10mg lutein, 2 mg zeaxanthin

The treatment assigned to you will be assigned by chance. You have a 2 in 3 chance of being assigned to Lumega Z or 1 in 3 chance to be assigned to PreserVision AREDS2. If positive effects are noted it is possible that the study may be extended. The tasks below are part of standard diagnostic clinical eyecare practice.

- Baseline, 3 month and 6 month examinations

  Medical History
  Best corrected visual acuity
  Best corrected contrast sensitivity (CSV-1000)
  Intraocular pressure, non dilated slit lamp exam
  Dark adaptation (AdaptDx, extended exam)
  Macular Pigment Optical Density (Mapcat SF)
  Macular Ocular Coherence Tomography (Cirrus OCT)
  Fundus Photography (Zeiss Procam)

If the Sponsor determines there is a need to extend the study, you may be asked to attend extra visits, although this is not required.

APPROVED BY SALUS IRB: 17 JANUARY 2018

LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS EXPECTED TO TAKE PART

Approximately 90 participants, ages 60 through 80, are expected to be in this study. The study will last for six months. At any point during the study, you may choose to withdraw with absolutely no penalty or questions asked. Your withdrawal will not jeopardize your relationship with the study doctor or the study staff at his clinic.

SIDE EFFECTS AND OTHER RISKS

There are no known side effects for the nutrients to be taken for this study. Lutein, zeaxanthin and meso-zeaxanthin have been studied in several thousands of people at various doses with no reports of side effects. Additionally, leutein, zeaxanthin and meso-zeaxanthin have no known drug interactions.

You must be honest in reporting anything out of the ordinary that you may experience during the study. There is a possibility that you may experience side effects from these nutrients.

UNFORESEEABLE RISKS

As noted above, there are no known risks associated with any of the procedures in the study. However, there is always a possibility that you may experience a side effect during the study. We ask that you please tell us if you believe this to be the case so that we can properly address the issue.

POSSIBLE BENEFITS OF THE STUDY

Lutein, zeaxanthin and meso-zeaxanthin could significantly reduce your risk for developing age-related macular degeneration or may delay, halt or even reverse the progression of the disease at its very earliest stages. You may also experience improvement in visual performance by participating in this study. Even if the study does not benefit you, this study could benefit other patients in the future. You will, receive a six months supply of lutein, zeaxanthin or lutein, zeaxanthin and meso-zeaxanthin at no cost.

PAYMENT FOR BEING IN THE STUDY

You will not be paid for being in this study.

ADDITIONAL COSTS

You do not have to pay for the specific study supplements. If the examinations conducted during the study would be conducted as a part of the routine care for macular degeneration, they would be submitted to your insurance plan and you would be responsible as usual, for expenses under deductibles and copays.

ALTERNATIVES TO PARTICIPATION

There are other treatments available if you decide not to be in the study.

APPROVED BY SALUS IRB: 17 JANUARY 2018

- You may choose to buy available supplements containing Lutein, zeaxanthin and meso-zeaxanthin.

- You may choose not to take any supplements at all.

RELEASE OF MEDICAL RECORDS AND PRIVACY

Your study records will be kept private. There may be times when the study doctor will not be able to guarantee privacy, such as when your study medical records are requested by a court of law or when shared with a firm in another country that does not have privacy regulations in place. Salus IRB and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, your total privacy cannot be guaranteed. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The following people will have access to your study records:

- Study Doctor
- Study Monitor or Auditor
- Sponsor Company or Research Institution
- Salus IRB
- Other State or Federal Regulatory Agencies

Salus IRB has approved this study and this informed consent document. Salus IRB is a committee of scientific and non-scientific individuals who review, require modifications to, and approve or disapprove research studies by following the federal laws. This group is also required by the federal regulations to provide periodic review of ongoing research studies.

IN CASE OF AN INJURY RELATED TO THIS RESEARCH STUDY

You must tell your study doctor if you feel that you have been injured by taking part in this study. You can tell the study doctor in person or call the number listed on the first page of this consent document. You will be treated with the same care that any other patient would receive if they suspected a side effect from treatment. No form of compensation is offered for a research related injury.

LEGAL RIGHTS

You do not lose any legal rights by signing this consent document. The above statement, "In Case of an Injury Related to This Research Study," does not stop you from seeking legal help in case of negligence.

NEW FINDINGS

During the study, you will be told of any important new findings about the nutrients used in the study. You can then decide if you still want to be in the study.

APPROVED BY SALUS IRB: 17 JANUARY 2018

WHOM TO CONTACT

You may contact the study doctor or study staff at the phone number listed on the first page of this consent document:

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

If you need medical attention please go to the nearest emergency room.

You may contact Salus IRB if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
2111 West Braker Lane, Suite 400
Austin, TX 78758
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: salus@salusirb.com

If you would like additional information about your rights, research in general, or IRBs, you may visit www.salusirb.com.

LEAVING THE STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. You have the right to leave this study at any time. If you do not want to be in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you wish to leave this study, please call the study doctor or study staff at the telephone number listed on the first page of this consent document to schedule study exit procedures.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- Study Doctor
- Sponsor Company
- Salus IRB
- Regulatory Agencies

If you do not follow the study procedures you may be taken out of the study.

APPROVED BY SALUS IRB: 17 JANUARY 2018

If you withdraw from the study, no new data about you will be collected for study purposes. The study doctor will inform you whether he/she intends to either: (1) retain and analyze already collected data relating to you up to the time of your withdrawal; or (2) honor your request that your data be destroyed or excluded from any analysis.

AGREEMENT TO BE IN THE STUDY

This consent document contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent document, please ask the person explaining this document or one of the study staff.

By consenting to participate you agree that you have been given a copy of all pages of this consent document. You have had an opportunity to ask questions and received satisfactory answers to all your questions about this study. You understand that you are free to leave the study at any time without having to give a reason and without affecting your medical care. You understand that your study-related medical records may be reviewed by the company sponsoring the study and by government authorities.

**IF YOU DO NOT AGREE WITH THE STATEMENT ABOVE,
YOU SHOULD NOT SIGN THIS INFORMED CONSENT DOCUMENT.**

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Explaining Informed Consent Document

_____ _____
Signature of Person Explaining Informed Consent Document Date

FOR Salus IRB USE ONLY
Initial draft cas: 02Nov17 tla: 17Jan18

CONTROLLED STUDY OF THE EFFECT OF A MEDICAL FOOD CONTAINING ALL THREE MACULAR CAROTENOIDS AND ESSENTIAL COFACTORS COMPARED TO AREDS2 ON EARLY MACULAR DEGENERATION

Sponsor: GUARDiON HEALTH SCIENCES, Inc.
15150 Avenue of Science, Suite 200
San Diego, California 92128
(800) 873-5141
Gordon Bethwaite
Vice President, Sales and Marketing

Investigator: Thomas T. Henderson, MD
3410 Far West Blvd. Suite 140
Austin, TX 78731
(512) 427-1100

Study Product: Lumega-Z Advanced Ocular Health Medical Food

Protocol Number: 1
Version 2
27 DEC 2017

Controlled Study of the Effect of a Medical Food Containing All Three Macular Carotenoids and Essential Cofactors Compared to AREDS2 on Early Macular Degeneration

PURPOSE:

This 6-month randomized control study is undertaken to compare the effect of treatment with LumegaZ, a medical food containing lutein, zeaxanthin, and meso-zeaxanthin, as well as essential cofactors, other antioxidants, and mitochondrial support, with the effect of treatment with AREDS2. Patients with early macular degeneration, defined as photographically visible drusen with or without abnormal dark adaptation on the AdaptDx will be randomized 2:1 and both groups will be compared to untreated patients with normal dark adaptation.

BACKGROUND:

Macular degeneration is the most common cause of blindness in people over the age of 60. The incidence of macular degeneration at all stages is 1 in 8 and is more common than diabetes and glaucoma at the same age.

The dietary carotenoids lutein and zeaxanthin (derived primarily from leafy green vegetables and other colored fruits and vegetables) as well as meso-zeaxanthin, a metabolite of lutein, are stored in the macula in all healthy retinas. This area serves central vison, and is the specific area that is affected by macular degeneration. The accumulation of these pigments results in a yellowish coloration of the retina, the concentration of which is called macular pigment density. A large multicenter trial called AREDS 2 (2013) showed that supplementing lutein and zeaxanthin reduced progression of moderate to advanced AMD by 25%. The CREST (2014) and MOST (2015) studies showed that supplementation of all 3 macular pigments resulted in normalization of the macular pigment profile and improvement in contrast sensitivity in early AMD. All 3 macular carotenoids are recognized by the FDA as 'generally regarded as safe (GRAS) for supplementation in foods.

Macular degeneration can be understood as a disease of excessive oxidation of the retinal tissue with genetic, age, dietary and light exposure components leading to accumulation of oxidized cholesterol and polyunsaturated fatty acids both on Bruch's membrane and between Bruch's membrane and the retinal pigment epithelium in a condition analogous to plaque

buildup in arteries. These deposits block transfer of waste out of the retina leading to more accumulation and block transfer of nutrients into the retina. In macular degeneration, not enough Vitamin A crosses Bruch's membrane because of the build-up, causing a localized deficiency of Retinol in the parafoveal rods. This causes slower dark adaptation after bleaching light, which is the earliest symptom of macular degeneration: difficulty driving in darkness or adapting to dark conditions increasing with aging.

Abnormal dark adaptation found by AdaptDX testing is the earliest clinical sign of macular degeneration. This has enabled diagnosis of subclinical macular degeneration with 90% positive and negative test reliability, 3-5 years before the first drusen is visible clinically. Those patients who exhibit impaired dark adaptation, whether they are subclinical with no drusen or early with mild drusen, may benefit from nutritional and /or lifestyle changes which could significantly slow the progression of the disease. This would result in maintenance of retinal health and visual performance.

It is clear that early, effective intervention in any disease process is the key to reducing morbidity. Earlier diagnosis of macular degeneration is now possible with AdaptDX testing. Effective intervention involves reducing the photo-oxidative damage of the retina caused by the visual process in the retina, and potential clearing of the early stage blockage of bidirectional transport across Bruch's membrane. Thirty percent of people over age 60 have abnormal dark adaptation. Likewise, 30% of people have an abnormal spatial profile of macular pigment indicating insufficient meso-zeaxanthin creation from lutein. Supplementing meso-zeaxanthin as well as lutein and zeaxanthin can restore the macular pigment spatial profile and improve visual performance in early macular degeneration. Early results from an as yet unpublished exploratory study in progress with such supplementation in subclinical AMD indicate improvement in MPOD and best corrected contrast sensitivity in many patients by 6 months.

A medical food is a special category of supplement approval by the FDA where physicians prescribe it for nutritional treatment of specific medical conditions. The medical food to be used by patients in this study contains not only all the macular carotenoids in micelle formulation for improved absorption, but also significant cofactors, such as vitamins, minerals, ALA, astaxanthin, N-acetylcysteine, carnosine and others. All of these ingredients working together should significantly improve the mitochondrial, antioxidant and anti-inflammatory functions of the retina. This should allow creation of less damage to critical elements of the retina and less toxic waste such as oxidized cholesterol and oxidized polyunsaturated fatty acids which are the major components of the sub-RPE and Bruch's membrane deposits. This controlled study will attempt to show that using a medical food designed to optimize retinal metabolism and antioxidant capacity will exert a positive effect in subclinical macular degeneration, which is greater than supplementation with AREDS2 and will also improve measured functions into the range of function in untreated normal patients.

STUDY:

All study candidates are routine patients in a general ophthalmology practice. All patients who are interested will be offered the opportunity to participate in this controlled study of the effect of a nutritional food on subclinical macular degeneration. Each patient will undergo a screening AdaptDx to separate patients with normal dark adaptation from those with abnormal dark adaptation. All patients will receive the same exams at baseline, 3 months and 6 months. For details, see the listing below. Those who are confirmed as normal with extended dark adaptation testing will receive no treatment precisely because they are defined as not having a problem needing this treatment. Those who are confirmed with early macular degeneration by photographically visible drusen and have dark adaptation scores of less than 10 minutes will receive treatment by ingesting a commercially available medical food, containing all 3 macular pigment as well as essential cofactors and other antioxidants, or AREDS2,randomized 2:1 for 6 months. If positive effects are noted, it is possible that the study might be extended. The tasks below are part of standard diagnostic clinical eyecare practice.

- Baseline, 3 month and 6 month examinations
  - History
  - Risk factors
  - Best corrected visual acuity
  - Best corrected contrast sensitivity (CSV 1000)
  - Intraocular pressure, nondilated slit-lamp exam
  - Dark adaptation (AdaptDX, extended exam)
  - Macular pigment optical density (MapcatSF)
  - Macular ocular coherence tomography (Zeiss Cirrus OCT)
  - Fundus photography (Zeiss VisuCam Pro)

Because these patients will have additional problems found in routine clinical practice, other exams may occur for other problems and will not be considered part of the study data. Should any adverse effects be noted thought to be from the study treatment, the patient will be examined to understand the effect and if it is felt to be not significant, the patient will be asked to continue in the study. In the highly unlikely event a serious adverse effect is noted the patient will be terminated from the study and appropriate treatment will be undertaken.

DATA COLLECTION:

The data will be maintained on standardized forms and printable graphics, as well as in the patient's routine clinical file. To protect identifiable information, files will be locked in a file cabinet, accessible only the PI and the study coordinator. Data will be transcribed without

personally identifiable information into standard Excel files and analyzed as appropriate using standard statistical techniques.

STUDY REQUIREMENTS:

This study will be conducted with the protocol, good clinical practices and applicable regulatory requirements. This is a no significant risk study, using commercially available supplements, Lumega-Z or AREDS2, containing 2 or 3 of the three carotenoids that are FDA “generally recognized as safe” for food supplementation and are found in all healthy retinas. All examinations are noninvasive and are performed with FDA cleared, commercially available medical devices in routine clinical use.

The study population consists of 90 male and female patients in a routine clinical practice age 60 and over who have early macular degeneration as defined as a few drusen visible on Visucam and have an AdaptDx score less than or equal to 10 minutes. No vulnerable populations will be studied.

The patient will be studied for improvements in ocular function. Primary endpoints would be improvement in macular pigment optical density long form, improvement in best corrected contrast sensitivity and improvement in best corrected vision. Secondary endpoints would be improvement of AdaptDx long form time or a reduction in drusen.

The study supplements for each

study subject will be kept in a locked cabinet until dispensed by study staff not involved with testing to the subject.

A protocol deviation log and an adverse effect log will be kept for each subject. Immediate attention will be paid to any serious adverse events, which by the nature of the study are completely unexpected. If any injuries occur to subjects in the protocol , they are considered to be under treatment for early AMD, (diagnosis AMD, ICD H35.3131) and will be dealt with as any other medical condition or complication of treatment.

Data will be reviewed for safety and unexpected positive or negative effects after three and six month visit period are completed for all subjects.

Data will be collected in the subjects routine electronic medical record and confirmed as complete on a hard copy visit log in a study folder for each subject. Copies of each visit will be kept in the study folder. There will be a protocol deviation log, adverse events log and a study supplement log in each subjects folder.

The information collected will be used in anonymous group data analysis to be prepared for submission for potential publication. The information will not be sold or used in future research. The data can be verified through the audit trail in the subject's individual electronic medical record original source. No data will be stored on a portable device. The data will not be destroyed because it is part of medical record of care of AMD unspecified for an individual and is subject to the laws of the state of Texas and the rules of the state medical board.

Salus IRB

INITIAL REVIEW (PROTOCOL)

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

If you require assistance answering any of the questions on this form, please contact the Salus IRB at the number listed above.

Sponsor: Guardion Health Sciences, Inc **Protocol #: ~~Lumgeaz #1~~** JT 31Oct 17

A. ADMINISTRATIVE INFORMATION:

How did you learn of Salus IRB?

☒ We are an existing client of Salus IRB ☐ Sponsor/CRO recommendation ☐ Tradeshow
☐ Industry Publication ☐ Internet/Website
☐ Other:

Sponsor Contact Information:

1.	Name of sponsor contact:	**Gordon Bethwaite**
2.	Sponsor name:	**Guardion Health Sciences, Inc**
3.	Telephone:	**(800) 873-5141**
4.	Email:	**gbethwaite@guardionhealth,com**

Provide the Primary Contact Information for IRB inquiries:

5.	Primary contact:	☐ Sponsor ☐ CRO ☒ Other: **PI**
6.	Name of primary contact:	**Thomas Henderson, MD**
7.	Name of company:	**Eye Clinic of Austin**
8.	Name of Project Manager (PM), if different than the primary contact:	**Valerie Gatavaski, COA, Study Coordinator**
9.	Address (including City, State and Zip):	**3410 Far West Blvd, Suite 140, Austin, TX 78731**
10.	Telephone:	**512-427-1100**
11.	Email:	**thenderson@eyeclinicofaustin.com**
12.	Include name and email addresses for additional study contacts, if needed:	**vgatavaski@eyeclinicofaustin.com** **Mo Livermore, Practice Administrator** **mlivermore@eyeclinicofaustin.com**

JT 31Oct17

Sponsor: Guardion Health Sciences, Inc	Protocol #: ~~LumgeaZ~~ #1

Provide the Accounts Payable contact information OR ☐ *Check if same as Primary Contact provided above.*		
13.	Name of accounts payable contact:	**Mo Livermore, Practice Administrator**
14.	Name of company:	**Eye Clinic of Austin**
15.	Address (including City, State and Zip):	**3410 Far West Blvd, Suite 140, Austin, TX 78731**
16.	Telephone:	**512-427-1107**
17.	Email: (All invoices will be sent via email)	**mlivermore@eyeclinicofaustin.com**
18.	Please list any additional requirements for invoicing (ex. PO numbers)	

B. FEDERALLY CONDUCTED OR SUPPORTED RESEARCH: ☒ N/A

1.	Identify the department/agency supporting the research: *Salus IRB currently does not review research funded by the following departments: Dept. of Defense, Dept. of Navy, Dept. of Justice, Dept. of Energy, Environmental Protection Agency* If federally conducted or supported, provide the following: ☐ a copy of the grant (if your company holds the grant) ☐ a copy of the DHHS approved protocol/study plan, if available ☐ a copy of the DHHS approved informed consent document (ICD), if available

C. PROTOCOL INFORMATION:

1.	Has this research been declined to be reviewed, disapproved, or tabled without a resolution by another IRB?	☒ No ☐ Yes (describe in an attachment)
2.	Has another IRB terminated this research?	☒ No ☐ Yes (describe in an attachment)
3.	Protocol/study plan version and date (including any Amendments) **Specify if this is a DRAFT protocol**:	**~~Draft~~ Protocol, LumegaZ Protocol #1, 10/15/2107**
4.	If this is a DRAFT protocol, include anticipated date of submission of the FINAL protocol.	FINAL Protocol 10 27-2017
5.	Therapeutic area/indication:	☐ Respiratory ☐ Hypertension ☐ Cardiovascular/Cardiology ☐ Dermatology ☐ Anti-Infectives ☐ Women's Health ☐ Urology ☐ Mental Health ☐ Other: ☐ Cosmetic ☐ Diabetes ☐ Infectious Disease ☐ Neurology ☐ Oncology ☒ Ophthalmology ☐ Pain Management ☐ Gastrointestinal

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Sponsor: Guardion Health Sciences, Inc **Protocol #: ~~Lumgeal #1~~** JT

6.	**Data and Safety Monitoring**: *A system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of participants and the validity and integrity of the data.* Data and safety monitoring will be conducted by: ☐ Data Safety Monitoring Board/Committee ☒ Principal Investigator (PI) ☐ Sponsor ☐ Other, please attach a description ☐ None, please attach a rationale
7.	Is the data and safety monitoring plan identified in the protocol? ☒ Yes, please identify the page #: **4-5** ☐ No, please describe your plan for monitoring safety and the integrity of the data:
8.	Will you ensure the site(s) have the necessary emergency or safety equipment to conduct the study in accordance with the protocol? ☐ No, please explain ☒ Yes ☐ N/A (for minimal risk research only)
9.	Will the study be posted to the ClinicalTrials.gov website? ☐ Yes ☒ No. If no, please provide a rationale: **non significant risk, but will post if requested/required**
10.	Please list all vulnerable populations specifically targeted in this research: ☒ NONE ☐ Children ☐ Children who are wards of State ☐ Pregnant women ☐ Non-English speaking ☐ Adults who do not read and/or write ☐ Patients in nursing homes ☐ Educationally disadvantaged ☐ Economically disadvantaged ☐ Employees or family members of the PI or sponsor ☐ Students of the university or the PI participating in this research ☐ Adults unable to consent for themselves or with diminished decision-making capacity (describe a plan to assess the capacity of these participants to consent/assent). ☐ Other:
11.	If any vulnerable populations have been identified, please describe the additional safeguards included in the protocol to protect the rights and welfare of these participants:

JT 31Oct17

Sponsor: Guardion Health Sciences, Inc	Protocol #: ~~LungeaZ #1~~

D. INFORMED CONSENT DOCUMENT INFORMATION:

1.	ICD submitted?	☐ No (skip to Waiver Requests section) ☒ Yes
2.	Will the protocol allow the sites to use an eConsent process? **If yes. This information may be found on page:**	☒ No ☐ Yes
3.	Are there any costs to the participants? **Additional costs must be disclosed in the ICD.**	☐ No ☒ Yes (Please describe in an attachment.)
4.	Will a HIPAA Authorization be a part of the ICD?	☐ No (skip to question 5) ☒ Yes
	If yes, will the authorization include permissions for future research?	☒ No ☐ Yes (please ensure an explanation is provided in the protocol)
5.	Request for a Waiver of Documentation of ICD?	☒ No ☐ Yes (Please complete a waiver request)
WAIVER REQUESTS		
6.	Request for a Waiver or Alteration of ICD?	☒ No ☐ Yes (Please complete a waiver request)
7.	Request for a Waiver of HIPAA Authorization?	☒ No ☐ Yes (Please complete a waiver request)

31Oct17 JT

Sponsor: Guardion Health Sciences, Inc **Protocol #: ~~LungeeZ-#1~~**

If you are a PM submitting for multi-site research, please complete the following sections.

If single-site, skip to the CERTIFICATION AND SIGNATURE section on the following page.

E. DOCUMENT DISTRIBUTION

Salus IRB is pleased to offer GlobeSync web-portal technology to our clients providing real-time, 24-hour password-protected access to study documents, which will serve as an on-line document repository for study duration. If selected as the distribution method for this research, Salus IRB will distribute all documents via GlobeSync.

Step 1: Please provide a list of names and email addresses of the individuals who are authorized to access study documents. If you require more contacts than the space below allows, please send additional contact information in a separate attachment.

Name	Email Address

Step 2: Each new user must request an account and create a username and password. To request an account:

- go to www.salusirb.com,
- select the GlobeSync button at the top of the screen,
- select "Request an Account", and
- follow the prompts to create your user information.

An email notification is sent to authorized users when study documents are available on GlobeSync. This notification will include a link to the secure site to allow access to the approved documents.

Please note: In order to ensure continued confidentiality of study documents, please notify Salus IRB of any staff changes that require us to disable GlobeSync access.

☒ Please check here if GlobeSync™ is not feasible for you. Please provide an email address in Section A for document distribution. Per Form 110B JT 31Oct17

F. STUDY MANAGEMENT:

1.	Number of total sites, per the protocol:	
2.	Number of sites to be submitted to Salus IRB:	
3.	Describe your plan to ensure the management of information that might be relevant to the protection of participants is appropriately communicated in a timely manner to the investigative sites and Salus IRB.	
4.	Who will be responsible for submitting study-wide notifications or modifications in the research, such as protocol revisions/amendments, product information updates, unanticipated problems, etc., to Salus IRB?	☐ Sponsor/Sponsor Representatives ☐ PI(s)

JT 31Oct17

Sponsor: Guardion Health Sciences, Inc **Protocol #: ~~Lumgeaz #1~~**

If you are a PM submitting for multi-site research, please complete the following sections.

G. RECRUITMENT MATERIAL:

1.	Will the sponsor provide template recruitment material for this research? See the *Guidance on Recruitment and Study Material* for additional instruction.	☒ No (skip to section H) ☐ Yes (identify below)
2.	Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file. The following template recruitment material is attached: ☐ Proposed printed advertisement, # ☐ Proposed web site content, # ☐ Script of proposed video recording, # ☐ Script of proposed audio recording , # ☐ Participant screening tool (phone screening) , # ☐ Other (describe/indicate quantity):	

H. STUDY MATERIAL:

1.	Will the sponsor provide template study material for this research? See the *Guidance on Recruitment and Study Material* for additional instruction.	☒ No (skip to section I) ☐ Yes (identify below)
2.	Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file. The following study material is attached: ☐ Participant diaries, # ☐ Survey instrument(s) or questionnaire(s), # ☐ Participant education material, # ☐ Additional material to be distributed to participants (e.g. non cash gifts for long-term retention) , # ☐ Other (describe/indicate quantity):	

I. TRANSLATION REQUESTS:

1.	Will the documents(s) require translation?	☐ No (skip this section) ☐ Yes
2.	Who will translate these documents?	☐ Salus IRB (complete #3) ☐ Sponsor or site (skip to next section)
3.	What documents would you like translated? What language would you like them translated into? Do you require a quote before proceeding with the translation? Do you require back-translation?	☐ ICDs ☐ Recruitment Material ☐ Study Materials Language: ☐ Yes ☐ No ☐ Yes ☐ No

31Oct17 JT

Sponsor: Guardion Health Sciences, Inc **Protocol #: ~~LumgeaZ~~#1**

CERTIFICATION STATEMENT AND SIGNATURE:

I certify that the information provided within this application, and applicable Supplemental Forms is true and accurate, and represents my intent to pursue review of this research by Salus IRB. I have reviewed the Investigator Reporting Responsibilities (single-site PIs) *or the* Salus IRB Sponsor Reporting Responsibilities (project managers), *and the* Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information *[Click hyperlink(s) above]. I understand I may contact Salus IRB at any time with questions or concerns about determinations and requirements. I grant Salus IRB the authority to review and oversee the above referenced research study and certify that the study will not begin until Salus IRB approval of the FINAL protocol and ICD. Further, I understand that only the Salus IRB-approved ICD may be used to enroll participants.*

Thomas Henderson, MD
Printed Name of Principal Investigator or Project Manager

Signature Date 10/26/17

LIST OF ATTACHMENTS:

REQUIRED DOCUMENTS:

☒ An electronic version (MS Word) of the proposed ICD(s) (main, foreign, assent, addendums)
☒ The current protocol (and any Amendments)
The completion of the appropriate Supplemental Forms, as appropriate.
- ☐ *FORM 100.A - Supplemental for Drug Research*
- ☐ *FORM 100.B - Supplemental for Device Research*
- ☒ *FORM 100.C Supplemental for Expedited Review of Minimal Risk Research*
- ☐ *FORM 100.D Supplemental for Exempt Research*
- ☐ *FORM 100.E Supplemental for International Research*

☒ **Attached explanation for ALL questions where a rationale or description are required.**

For Recruitment and Study Material: Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file.
☐ All proposed study material (diaries, survey instruments, or questionnaires)
☐ All proposed recruitment material (audio/video script, print advertisement)

Salus IRB

SUPPLEMENTAL FOR DRUG RESEARCH

Sciences Inc. JT 31Oct17

Sponsor: Guardion Health	Protocol #: ~~LumegaZ protocol~~ 1

For studies using two or more drugs, provide this form for each drug:

1.	Is this a "first in human" use?	☒ No ☐ Yes (first or no human data is available)
2.	What is the phase of this study?	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☒ Other: **supplement**
3.	*Drug Name:*	**LumegaZ**
4.	To what class does this drug belong?	**medical food** **Or** ☐ Radio-labeled (See additional submission requirements below)
5.	Is this study being conducted under an IND?	☐ Yes (proceed to question 6) **OR** ☒ No, this study is exempt from the requirement of an IND, as described in 21 CFR 312.2(b) ☐ Attach exemption category rationale and proceed to question 9.
6.	Drug IND #	☐ # or ☐ Pending; Date the application was submitted to the FDA:
7.	Who holds this IND?	☐ Sponsor ☐ Investigator - If the Investigator holds the IND, please provide a written assurance (unless documented in the protocol) signed by the Investigator, that the Investigator will conduct the research as both the Sponsor and the Investigator, in compliance with the Sponsor and Investigator regulations in 21 CFR 312, in addition to 21 CFR 50, 56.
8.	Verification of the IND is supported by (the IB may not be used to verify the IND#):	☐ Sponsor's protocol imprinted with the IND # ☐ Written communication from the Sponsor or FDA indicating the IND # (attached)
9.	Investigator's Brochure or equivalent included?	☐ No ☐ Yes - Version and Date:
10.	Is the study drug formulation approved by the FDA? If yes, please attach the product information, PDR, etc.	☐ No ☒ Yes Version and Date (if appl.): received 27Oct17
11.	Will females be excluded from participating in this study? ☐ Yes ☒ No **If yes,** please attach a medical/scientific rationale for this exclusion.	JT 31Oct17

Supplement do not need IND JT 31Oct17

LIST OF ATTACHMENTS:

REQUIRED DOCUMENTS:

- ☐ For Investigational DRUG studies only: Investigator's Brochure (or equivalent Safety Information).
- ☒ For DRUG studies using approved drugs: The current Package Insert (for each approved drug used in this study)
- ☐ For ALL studies with an IND: Documentation from the Sponsor or the FDA that verifies the IND number (the protocol may serve as documentation if the protocol is imprinted with the IND #)
- ☐ **Attached explanation for ALL questions where a rationale or description is indicated.**

For Radio-labeled research:

- ☐ Radiation Safety Committee (RSC) approval letter **OR** Dosimetry report showing that the anticipated human radiation dose will be below the FDA maximum exposure level.
  - Include estimated millirem exposure.
  - If the letter does not include dosimetry, please ensure the information is provided in another document, such as the protocol.

Salus IRB

Sciences Inc.

SUPPLEMENTAL FOR EXPEDITED REVIEW OF MINIMAL RISK RESEARCH

Sponsor: Guardion Health **Protocol #:** ~~**LumegaZ protocol**~~ **1**

JT 30oct17

Name of Principal Investigator or Project Manager: Thomas Henderson, MD, principal investigator

This form must be submitted in addition to the appropriate submission forms for Initial Review.

Certain types of research may be reviewed and approved through an expedited review process. A primary criterion is that the research be of minimal risk only. Minimal risk is defined as *the probability and magnitude of harm or discomfort anticipated in the research are not in and of themselves greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* Additionally, the purpose of the research must fit within a series of categories as stipulated by FDA (21 CFR 56.110) and DHHS regulations (45 CFR 46.110).

A. APPLICABILITY:

To determine whether a research project qualifies for expedited review, the protocol must indicate that the research activities fulfill requirements A and B, and one of the categories outlined under C. For a protocol to be considered for expedited review, please check A and B and the appropriate category under C.

☒ A. The research activity poses no greater than minimal risk; **and**

☒ B. The identification of the subjects and/or their responses would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal; **and**

☒ C. The research falls under one or more of the expedited categories below. **Please check all that apply.**

☒ **Category 1.** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Category 2.** Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:

(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period **AND** collection may not occur more frequently than 2 times per week; **or**

(b) From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period **AND** collection may not occur more frequently than 2 times per week.

Guardion Health Sciences Inc.
Thomas Henderson, MD
JT 30 Oct 17

Salus IRB

SUPPLEMENTAL FOR EXPEDITED REVIEW OF MINIMAL RISK RESEARCH

☒ **Category 3.** Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☒ **Category 4.** Collection of data through noninvasive procedures (not involving a general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ **Category 5**. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

☐ **Category 6**. Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **Category 7**. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Salus IRB

INVESTIGATOR AND SITE INFORMATION

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

FORM 110.A will be saved in our Investigator files for future reference. ***Please notify Salus IRB of any changes to the information supplied here as soon as it becomes known to the site/Investigator (PI).*** *If you require assistance answering any of the questions on this form, please contact the Salus IRB at the number listed above.*

INVESTIGATOR: Thomas Henderson, MD

A. SITE CONTACT (for IRB inquiries):

1.	Primary contact name:	**Thoma Henderson, MD**
2.	Research site name:	**Eye Clinic of Austin**
3.	Phone number:	**512-427-1100**
4.	E-mail (please include email addresses for additional study contacts, as needed):	**thenderson@eyeclinic2020.com** **vgatavaski@eyeclinicofaustin.com** **mlivermore@eyeclinicofaustin.com**

B. PRIMARY RESEARCH SITE INFORMATION:

1.	Name of research site **(Site 1)**:	**Eye Clinic of Austin**
2.	Site address (including City, State and Zip):	**3410 Far West Blvd, Suite 140, Austin,TX 78731**
3.	Site 24 hour phone number for participants:	**512-427-1100**
4.	PI's direct phone number for board inquiries:	**512-422-2903**
5.	PI's email:	**thenderson@eyeclinic2020.com**
6.	**For Drug or Device Research**: Check all emergency or safety equipment currently available at this site to treat life threatening allergic reactions: ☒ Anaphylactic Shock Kit ☒ CPR Trained Personnel ☐ Full Crash Cart ☐ Other (describe):	

C. ADDITIONAL RESEARCH SITES OR ☒ *N/A OF NONE*:

Provide information for each additional research ***site.*** *Identify any place other than the main site such as hospitals, clinics or private practices where any research procedures may be performed (as it could be listed in box 3 of Form FDA 1572, if applicable).*

1.	Name of **Site 2**:	
2.	Complete Address (including City, State and Zip):	
3.	**For Drug or Device Research:** Check all emergency or safety equipment currently available at this site to treat life threatening allergic reactions: ☐ Anaphylactic Shock Kit ☐ CPR Trained Personnel ☐ Full Crash Cart ☐ Other (describe):	

For PIs with more than 2 sites, please provide the additional site information in an attachment.

4.	Number of additional sites being submitted in attachment, if applicable:	

INVESTIGATOR: Thomas Henderson, MD

D. PRINCIPAL INVESTIGATOR CREDENTIALS AND RESOURCES

1.	The following documents must be included with this submission:	☐ The PI's current professional license ☒ already on file ☐ The PI's current CV ☒ already on file ☐ PET-abc Records. Please list email address used to access these records:
2.	For DRUG studies taking place in Massachusetts, include:	☐ MA Researcher license ☐ already on file ☐ DEA license (controlled substance) ☐ already on file
3.	Is there any pending disciplinary action against the PI from ANY state licensing board?	☒ No ☐ Yes (attached)
4.	Describe the PI's process for ensuring that all persons assisting with the research are adequately informed about the protocol, the investigational product(s), and their study related duties and functions: **specific training and active clinical research coordinator**	
5.	Describe the setting in which the research activity will take place: **Clinical ophthalmology office**	
6.	**Privacy refers to persons and their interest in controlling the access of others to themselves.** Describe the plan to protect the privacy of research participants, during and after their involvement in the research. • Participants consented away from the public areas • Study-related assessments conducted in a private area • Participant information collected is limited to study requirements • Additional provisions (describe): **locked files**	☒ Yes ☐ No ☐ Yes ☒ No ☒ Yes ☐ No
7.	If no was indicated on any of the first 3 responses above, please provide an explanation: **uses routine clinical examination techniques to obtain data, doors closed**	
8.	**<u>Confidentiality</u> refers to the agreement between the PI and participant in how the participant's identifiable private information will be managed and used.** Describe the plan to maintain the confidentiality of the data collected <u>during</u> and <u>after</u> the research is complete (check all that apply) ☒ Paper files will be kept in a secure location with limited access by authorized study staff ☒ Electronic files are password-protected with limited access by authorized study staff ☒ Participant's identifying information will be protected from improper use and disclosure (e.g. coding, making data anonymous) ☒ Research staff sign confidentiality agreements <u>before</u> engaging in research activities ☒ The site will not use the collected information outside of that specifically consented to and authorized ☐ Other (describe):	

INVESTIGATOR: Thomas Henderson, MD

E. PI EXPERIENCE AND TRAINING:

It is the PI's responsibility to ensure that all research staff assisting in the conduct of this research are informed about their obligations in meeting the requirements of 21 CFR Parts 50, 56 and 45 CFR 46, and have the training and education to follow the requirements.

1.	Has the PI completed human subject protection training?	☐ No ☐ Yes, attached ☒ Yes, already on file
2.	Do any other members of the PI's staff, including Sub-Investigators, have any human subject protections training?	☐ No ☒ Yes
3.	How many years has the PI been conducting research?	**35**

F. REGULATORY INSPECTIONS:

1.	Are there any pending or active legal, regulatory, or professional actions or restrictions related to the practice of medicine or research at the site?	☒ No ☐ Yes, attached
2.	Has the PI or any members of the research staff been disciplined or restricted by the FDA, DHHS or other regulatory agencies?	☒ No ☐ Yes, attached
3.	Has the PI been subject to an FDA, DHHS or other regulatory agency inspection within the past 2 years? **If yes, please provide inspection findings and site response or written notification from the agency.**	☒ No ☐ Yes, attached ☐ Yes, already on file
4.	Has the PI been debarred by the FDA, DHHS or other regulatory agency?	☒ No ☐ Yes, attached

G. INFORMED CONSENT DOCUMENT (ICD) INFORMATION or ☐ N/A:

Complete this section for consenting procedures (for all participants) at your site.
OR
Attach your site specific SOP regarding the consent process. ***If submitting a SOP, please complete the questions below for any items not addressed in your SOP.***
OR
☐ *SOP(s) on file*

1.	Who will present the ICD to the potential research participant and conduct the consent interview at this site?	☐ PI ☐ Sub Investigator ☒ Research Coordinator/Research Nurse ☐ Other:
2.	What steps will you take to minimize the possibility of coercion or undue influence? **Prospective subjects are made aware of the their right to freely choose or not to choose to participate in this study with no consequence and that there is no financial gain in participating in this study**	
3.	Will prospective participants be allowed to take the ICD home to discuss this research with their family or Primary Care Physician?	☒ Yes ☐ No (please explain in attachment)
4.	Describe the timeframe between approaching the prospective participants and obtaining informed consent: **Timeframe may vary from a few days to a few weeks depending on the availability of the subject and study appointments**	
5.	Describe who will assist the PI in ensuring informed consent is appropriately obtained and documented and for ensuring that a copy is provided to the participant: **research coordinator**	

INVESTIGATOR: Thomas Henderson, MD

INVESTIGATOR STATEMENT OF AGREEMENT:

As the PI, I accept full responsibility for:

1. Reviewing the protocol (and Investigator's Brochure, if applicable) in its entirety, and conducting the research according to the Salus IRB approved protocol. Ensuring that all research staff complies with the requirements of the protocol.

2. Ensuring adequate and reliable financial and/or other resources are available to conduct research and halt research procedures should any of these resources become unavailable.

3. Ensuring that I and all research staff assisting in the conduct of research are informed about their obligations in meeting the requirements of 21 CFR Parts 50, 56 and/or 45 CFR 46, and ICH-GCP 4.1-4.13 as applicable and have the training and education to follow the requirements. Ensuring consideration of all applicable federal regulations, local and/or state laws pertinent to the research site, and consideration of community attitudes in terms of religious, ethnic, or economic status of the community from which research subjects will be drawn, relative to research at my site.

4. Ensuring that no member of the study staff (*or their immediate family's*), including sub-Investigators, has an actual or perceived Conflicts of Interest (COI) with any study, and if one is present that it will be effectively managed so to not interfere with the study progression and data.

5. Providing a copy of the Salus IRB approved ICD to research participants at the time of consent, and for not enrolling any individual into research until voluntary consent has been appropriately obtained and documented. Ensuring that each potential subject is provided with the information needed to understand the nature and potential risks of the research, and for taking necessary steps for the individual to gain that comprehension.

6. Ensuring that no individual is recruited into research: (a) until the study has been approved in writing by Salus IRB; (b) during any period wherein Salus IRB approval of a research study has lapsed; (c) during any period wherein Salus IRB approval of research or participant enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; (d) following termination of Salus IRB approval of research; or (e) following expiration of the approval period as established by Salus IRB.

7. Promptly assessing and reporting all unanticipated problems to Salus IRB within the required timeframe, and ensuring that participants who have suffered an unanticipated problem or adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the event to the extent possible. Arranging for the treatment of a research related injury with the sponsor, when applicable.

8. Promptly reporting all proposed changes in previously approved research to Salus IRB. Making no changes in approved research except when necessary to eliminate an apparent immediate hazard to research participants. Making no changes to the information provided to research participants (potential or active), such as ICD, recruitment or study material in electronic or print format. Promptly reporting any changes in the PI's address or other contact information and seeking approval for an additional research facility prior to initiation of study procedures at that facility. Promptly reporting any changes to the Financial Disclosure/COI information that was initially disclosed; or occurrences of undue influence.

9. Ensuring that research participants are kept fully informed of any new information that may affect their willingness to continue participation in the research. For responding appropriately and adequately to all inquiries, complaints, or concerns from research participants. Promptly reporting any changes to the participant population, or in the vulnerability of participants to Salus IRB.

INVESTIGATOR: Thomas Henderson, MD

10. Maintaining each participant's information in such a way as to protect the privacy of the individual and the confidentiality of the data.

11. Seeking timely review and approval for continuing the research in accordance with 21 CFR 56.109(f) or 45 CFR 46.109(e), prior to the expiration date to avoid non-compliance with Salus IRB policies or administrative closure of the research. Notifying Salus IRB upon completion of the research and promptly submitting a Final/Closeout Report, as it applies to my research, prior to the expiration date of the approval period. Responding promptly to all requests for information or materials from Salus IRB board members or staff.

12. For research involving investigational products (IP) (drugs/devices): Administering the IP only to participants under my supervision or the supervision of my designee(s). Supplying the IP only to those individuals who are authorized to receive it.

13. I understand that **Finder's fees** (referral fees) provided by the PI/sponsor to research staff or other Physicians for potential participant referrals are not allowed by Salus IRB. Salus IRB will allow the sponsor or PI to pay a referral fee to a research participant for referring another research participant and some stipulations may apply. I further understand that **Recruitment bonuses** (payments from the sponsor to an PI or organization designed to accelerate recruitment based on the rate or timing of participant enrollment) should be disclosed to Salus IRB and will be considered by Salus IRB on a case-by-case basis.

My signature below indicates that;

- ☒ **I agree to assume the responsibilities for the safe and ethical conduct of research and to abide by the decisions and requirements of Salus IRB;**
- ☒ **I have reviewed the *Investigator Reporting Responsibilities* and the *Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information*. [Click hyperlink(s) above];**
- ☒ **If study staff/Sub-Investigators are permitted to sign research documents in lieu of the PI, I understand it is my responsibility to ensure that the delegated staff are notified of the reporting requirements;**
- ☒ **I may contact Salus IRB at any time with questions or concerns about these requirements;**
- ☒ **The information provided on this document is true and accurate to the best of my knowledge;**
- ☒ **It is my responsibility to notify Salus IRB if any of the information contained in this form should change.**

Signature of Principal Investigator: Henderson MD Date: 10/26/17

LIST OF ATTACHMENTS:

REQUIRED DOCUMENTS:

Once the following information is submitted to Salus IRB, it will be saved in the Investigator file for future reference

- ☒ The PI's current professional license
- ☒ The PI's current CV
- ☒ Documentation of GCP training for PI
- ☐ **Attached explanation for any question answered "Yes" that requires an attachment**

ADDITIONAL REQUIRED DOCUMENTS FOR DRUG STUDIES CONDUCTED IN MASSACHUSETTES:

- ☐ Unless already on file, current DEA License (Controlled Substance Registration Certificate) AND Researcher License.

Salus IRB

PROTOCOL SPECIFIC INVESTIGATOR AND SITE RESOURCES

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

If you require assistance answering any of the questions on this form, please contact the Salus IRB at the number listed above.

Sciences Inc.

SPONSOR: Guardion Health **PROTOCOL #: ~~LumegaZ Protocol~~ 1**

INVESTIGATOR: Thomas Henderson, MD JI 310c+17

A. SITE CONTACT for IRB inquiries:

1.	Primary contact name:	**Thomas Henderson, MD**
2.	Research site name:	**Eye Clinic of Austin**
3.	Phone number:	**512-427-1100**
4.	Email (please include email for additional study contacts, as needed):	**thenderson@eyeclinic2020.com** **vgatavaski@eyeclinicofaustin.com** **mlivermore@eyeclinicofaustin.com**

B. DOCUMENT DISTRIBUTION

Salus IRB is pleased to offer GlobeSync web-portal technology to our clients providing real-time, 24-hour password-protected access to study documents which will serve as an on-line document repository for study duration. If selected as the distribution method for this research, Salus IRB will distribute all documents via GlobeSync.

Step 1: Please provide a list of names and email addresses of the individuals who are authorized to access. If you require more contacts than the space below allows, please send additional contact information in a separate attachment.

Name	Email Address

Step 2: Each new user must request an account and create a username and password. To request an account:

- go to www.salusirb.com,
- select the GlobeSync button at the top of the screen,
- select "Request an Account", and
- follow the prompts to create your user information.

An email notification is sent to authorized users when study documents are available on GlobeSync. This notification will include a link to the secure site to allow access to the approved documents.

Please note: In order to ensure continued confidentiality of study documents, please notify Salus IRB of any staff changes that require us to disable GlobeSync access.

☒ Please check here if use of GlobeSync is not feasible for you. Please provide an email address in Section A for document distribution.

C. REGULATORY AGENCY:

1.	If the research is federally funded or supported, **OR** the research will be conducted under your institution's FWA, please supply the following information:	☒ N/A ☐ IRB Authorization Form (please complete the authorization form found on the Salus IRB website) ☐ FWA# ☐ Please submit a copy of the FWA on file with OHRP

~~For~~ Guardion Health Sciences Inc.
Thomas Henderson, MD
Protocol #: 1

JT 31Oct17

Blank

Sciences Inc.

SPONSOR: Guardion Health **PROTOCOL #:** ~~LumogaZ Protocol~~ 1

INVESTIGATOR: Thomas Henderson, MD JT 31Oct17

D. RESEARCH SITE INFORMATION (as compared to *FORM 110.A Investigator and Site Information*):

All sites where research procedures will be performed must receive IRB approval and should be listed on the site specific informed consent document (ICD).

1.

☒ All sites identified on Form 110.A will be used for this research;
☐ Only the following site(s) identified on Form 110.A will be used for this research;
Site name(s) -
☐ In addition to those site(s) identified on Form 110.A, the following site(s) *not* previously identified will be used for this research. Please complete **Question A** below. [If the following site(s) will be used for research in the future, please consider submitting an updated Form 110.A]
☐ None of the site(s) identified on Form 110.A will be used for this research. Please complete **Question A** below. [If the following site(s) will be used for other research in the future, please consider submitting an updated Form 110.A]

A. Additional/New Site (if there is more than one (1) site, please supply this same information in an attachment):
Site name(s) -
Site address -
24-hour number (to be listed on the ICD) -
List procedures to be done at this site -

E. IRB JURISDICTION:

1.	Is the research site(s) under the jurisdiction of a local IRB (*e.g., hospital, university, surgery center, or network)*?	☐ No (Please provide the Institutional Official's signature below) ☐ Yes (Please provide the IRB Chair's signature below) ☒ N/A (*Site is a private practice/clinic)* Skip to section F.

Institutional Official or Designee:

I validate that this institution does not have an IRB and that Salus IRB may serve as the IRB of record for this research.

Name of Institution:

Printed Name:

Title:

Signature:_____ Date:_____

IRB Chair or Designee:

I am aware that study-related procedures for the above referenced research will be conducted at our institution, and I hereby defer authority to Salus IRB to serve as the IRB of record for this research.

Name of Institution:

Printed Name:

Title:

Signature:_____ Date:_____

Sciences Inc

SPONSOR: Guardion Health **PROTOCOL #: ~~LumegaZ Protocol~~ 1**

INVESTIGATOR: Thomas Henderson, MD JT 31Oct17

F. RECRUITMENT PRACTICES, MATERIAL:

1.	Describe how prospective research participants will be identified and approached for this study: **patients in clinical practice asked with explanation of research if they would be willing to participate**	
2.	Will the site make use of recruitment material for this research? See the *Guidance on Recruitment and Study Material* for additional instruction. **Please do not submit template material already submitted for approval by the sponsor/project manager (PM).**	☒ No (skip to question #4) ☐ Yes (identify below)
3.	Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file. The following recruitment material is attached (please include quantity of each): ☐ Proposed printed advertisement, # ☐ Proposed web site content, # ☐ Script of proposed video recording, # ☐ Script of proposed audio recording, # ☐ Participant screening tool, # ☐ Other (describe, include quantity):	

Research Participant Finder's Fees/Referral Fees: Such arrangement may place participants at risk of coercion or undue influence or cause an inequitable selection of research participants. Salus IRB will consider these types of requests on a case-by-case basis.

- The payment arrangement for the referral must be approved by the board and should be disclosed in the ICD or addendum.

Finder's fees paid to PIs or other physicians are never allowed.

4.	Is the PI or sponsor providing a finder's fee or referral fee to participants for potential participant referrals?	☒ No ☐ Yes
5.	If yes, please describe your policy regarding these fees and include the amount of the fee (or indicate if already on file with Salus IRB).	

G. STUDY MATERIAL:

1.	Will the site make use of study material for this research? See the *Guidance on Recruitment and Study Material* for additional instruction. **Please do not submit template material already submitted for review by sponsor/PM.**	☒ No (skip to section H) ☐ Yes (identify below)
2.	Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file. The following study material is attached (please include quantity of each): ☐ Participant diaries, # ☐ Survey or questionnaire(s), # ☐ Participant education material, # ☐ Other (describe, include quantity):	

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SPONSOR: Guardion Health **PROTOCOL #:** ~~LumegaZ Protocol~~ 1

INVESTIGATOR: Thomas Henderson, MD JT 31Oct17

H. TRANSLATION REQUESTS:

1.	Will the documents require translation?	☒ No (Go to section I) ☐ Yes
2.	Who will translate these documents?	☐ Salus IRB (complete #3) ☐ Site (skip to question 4)
3.	What documents would you like translated? What language would you like them translated into? Do you require a quote before proceeding with the translation? Do you require back-translation?	☐ ICDs ☐ Recruitment Material ☐ Study Material Language: ☐ Yes ☐ No ☐ Yes ☐ No
4.	Describe your plan for recruiting and enrolling non-English speaking participants: **not expecting to recruit**	
5.	What language(s) do those obtaining consent speak? **English**	

I. PI RESOURCES: NA JT 31Oct17

1.	The following documents must be included with this submission:	☐ Form FDA 1572 (Investigational DRUG studies only) **Note: Please DO NOT send original Form FDA 1572** ☐ PI's Commitment to sponsor (For Device studies only)
2.	Does the PI have access to the necessary population and number of participants needed for this study, within the agreed recruitment period?	☐ No ☒ Yes
3.	Does the PI have the sufficient time to properly conduct and complete the study within the agreed study period?	☐ No ☒ Yes
4.	Does the PI have an adequate number of qualified staff, and adequate facilities for the duration of the study, to conduct the study properly and safely?	☐ No ☒ Yes
5.	Describe additional resources available at this site to support the conduct and successful completion of this study: **all clinical examination devices necessary for study**	

J. PI EXPERIENCE AND TRAINING:

1.	Please describe any previous experience or training that the PI has which will aide in the conduct of this study: **Macuhealth protocol 1, 35 years of experience**	
2.	Will Sub-Investigators perform procedures the PI is not qualified and licensed to perform?	☒ No ☐ Yes (please attach the CV and licenses of those Sub-I's)
	Please describe those procedures:	

Sciences Inc.

SPONSOR: Guardion Health **PROTOCOL #: ~~LumegaZ Protocol 1~~**

INVESTIGATOR: Thomas Henderson, MD JT 31 Oct 17

K. REQUIRED SAFETY AND EMERGENCY MEDICAL EQUIPMENT AND PSYCHOLOGICAL RESOURCES:

1.	Describe your plan for treating medical emergencies or providing counseling or additional psychological support that may be needed as a consequence of the research: **none expected but fully equipped and trained for emergencies**
2.	Do you have a written agreement with the sponsor that addresses medical care for research related injuries? *This information will be disclosed in the ICD.* ☐ Yes - Attach page from the contract, a statement from the sponsor, or a written explanation ☒ No - Explain your plan for addressing medical care for research related injuries See ICD
3.	**Drug/Device Storage and Handling**: ☐ N/A – this study does not involve any drug or device JT 31 Oct 17 If the study involves drug(s) or device(s), which of the following measures will be followed? Check all that apply for each section. a. ☒ All drugs/devices will be stored appropriately in a secure area ☐ pharmacy or central area ☒ locked storage unit, cabinet or office ☐ Other: b. ☒ Access to the drugs/devices will be limited to authorized research personnel ☒ use of log indicating authorized personnel for controlled access ☐ Other: c. ☒ Accountability records will be adequately recorded and maintained d. ☒ Who is responsible for dispensing the drug/device? ☐ PI ☐ Pharmacy personnel ☒ Other: **study coordinator** When appropriate, describe additional plans for the secure storage, handling and dispensing of drug(s) or device(s):

Sciences Inc.

SPONSOR: Guardion Health **PROTOCOL #: ~~LumegaZ Protocol~~ 1**

INVESTIGATOR: Thomas Henderson, MD JT 31Oct17

L. DATA PROTECTIONS AND CONFIDENTIALITY:

1.	Will eConsent be utilized for this research? **If yes, please provide a written statement or SOP confirming the eConsent process is Part 11 compliant.**	☒ No ☐ Yes
2.	**Sensitive Information**: *Information which may upset the individual being asked about the information, or that if misused, could reasonably cause discrimination or stigmatism, and result in damage to the individual's financial well-being, employability, insurability, or reputation.* Will sensitive information be collected for this research? Examples include: • Use or treatment for alcohol or drugs • Illegal conduct or arrest record • Sexual attitudes, preferences or practices • Psychological or mental health information • HIV or sexually transmitted diseases	☒ No ☐ Yes
3.	Will sensitive or individually identifiable health information, including demographic information, be collected using web-based tools, email, online surveys, etc.?	☒ No (skip to section M) ☐ Yes
	If yes, the website or online tool should clearly explain how the information might be used and what measures will be taken to ensure confidentiality of their data. Attach the text version of the online tool for IRB approval.	
	How long will the information be stored? **locked cabinet and password protected EMR**	
	If the participant does not qualify for the research, what will happen to their data?	
	Will the information be stored and used in the future? **If yes, please explain.**	☒ No ☐ Yes
	Will the information be sold to 3rd parties? **If yes, please explain.**	☒ No ☐ Yes
4.	What security methods are in place to ensure protection of the sensitive information (check all that apply): ☐ Replace the identifiers with a unique code and storing identifiers in a separate location and/or device ☒ Never store identifiers on portable electronic devices, such as laptops, portable hard drives, flash drives, USB memory sticks, and smart phones, unless devices are encrypted ☒ PHI will be transferred only over secure networks or as encrypted files ☐ PHI will only be transferred using encryption ☐ Remove and destroy identifiers as soon as possible ☐ De-identification: once data has been de-identified, it no longer qualifies as PHI ☐ Destruction of data. At what point will data be destroyed? **permanent part of medical record** ☐ Other: **data analysis will be done with de identified data**	

Sciences Inc.

SPONSOR: Guardion Health PROTOCOL #: ~~LumegaZ Protocol~~ 1

INVESTIGATOR: Thomas Henderson, MD JT 31Oct17

M. VULNERABLE POPULATIONS:

1.	**Please indicate all vulnerable populations that will be enrolled or may be specifically targeted for this research. IRB approval is required for the enrollment of vulnerable populations. If you decide to enroll persons from any of these categories at a later time, you may request IRB approval at that time.** ☒ None ☐ Children (defined as individuals who have not reached the legal age under State Law to consent to the treatments or procedures in this research); **(complete CHILDREN questions below, if applicable)** ☐ Children who are wards of State **(complete CHILDREN questions below, if applicable)** ☐ Pregnant women ☐ Non-English speaking ☐ Adults who do not read and/or write **(complete LAR question below, if applicable)** ☐ Patients in nursing homes **(complete LAR question below, if applicable)** ☐ Educationally disadvantaged ☐ Economically disadvantaged ☐ Employees or family members of the PI or sponsor ☐ Students of the university or the PI participating in this research ☐ Other:
2.	For each vulnerable population identified above, please provide your justification for including these populations in this study:
3.	Describe the additional safeguards in place to protect the rights and welfare of these participants:

STUDIES ENROLLING CHILDREN OR ☒ **N/A** (IF NOT ENROLLING):

1.	In your state, what is the legal age to consent to the treatments or procedures involved in this research?	Age:
2.	In your state, are <u>both</u> parents required to consent on behalf of the child?	☐ No ☐ Yes
3.	Do you plan to obtain permission for children from individuals other than the parents?	☐ No ☐ Yes
4.	If yes, other than the parents, who is legally authorized in your state to consent on behalf of a child?	
5.	For Drug or Device Research: Is this facility equipped to handle pediatric emergencies?	☐ No ☐ Yes ☐ N/A

Sciences Inc

SPONSOR: Guardion Health **PROTOCOL #:** ~~LumogaZ Protocol~~ 1

INVESTIGATOR: Thomas Henderson, MD JT 31 Oct 17

STUDIES USING *LEGALLY AUTHORIZED REPRESENTATIVE* (LAR); (If the research you are participating in allows LARs for participants other than children) **OR** ☒ **N/A** (NOT UTILIZING LARs):	
1.	Who may serve as an LAR to provide consent for procedures performed in research?

N. STATE AND LOCAL RESEARCH LAWS:

Please indicate any state or local laws regarding medical research and/or vulnerable populations that may affect the conduct of the study or that require additional information to be included in the ICD (e.g., separate state mandated HIV ICDs, mandatory reporting of positive HIV/hepatitis results).

none

O. COMMUNITY ATTITUDES AND INFORMATION:

1.	Are there any community attitudes (including religious, ethnic, etc.) about medical research that may affect the conduct of this study or that may be sensitive to the community? **If yes, please attach a description.**	☒ No ☐ Yes

P. PAYMENT ARRANGEMENTS:

The following will be used to customize the ICD for your site:		
1.	Will participants be paid for their participation?	☒ No (skip to question 6) ☐ Yes
2.	Please provide the breakdown (per visit/procedure) for compensation to the subject (i.e., $25 for visit 1, $50 for visit 2, etc.):	
3.	Approximately when should the participants expect payment? ☐ Payment at each study visit ☐ Payment at the participant's final visit ☐ Payment after the participant completes the study within the following time frame: ☐ Other (describe):	
4.	Total potential compensation for completion of protocol requirements:	
5.	Is an end of study bonus being offered to participants? *Ensure the amount does not exceed 50% of the total payment for completion of the research.*	☐ No ☐ Yes (amount):
6.	Is the PI receiving a "recruitment bonus" from the sponsor based on the rate or timing of enrollment? If yes, please attach a description of the financial arrangement and disclose this information in the Conflicts of Interest (COIs) section.	☒ No ☐ Yes

Sciences Inc.

SPONSOR: Guardion Health PROTOCOL #: ~~LumegaZ Protocol~~ 1

INVESTIGATOR: Thomas Henderson, MD JT 31Oct17

CONFLICTS OF INTEREST:

The PI is responsible for reading each statement thoroughly before signing this form. Please consider any potential, actual, or perceived conflicts of interest (COIs) of a financial, professional, or personal nature with the sponsor, test article, or manufacturer of the test article, that may affect any aspect of *this research*. The responses *must* also consider any COIs of the PI's immediate family members. Salus IRB defines "immediate family member" as (at a minimum) an individual's dependent children *or* a person with whom an individual lives, in the same residence, where both individuals share responsibility for each other's welfare and financial obligations (e.g., spouse, domestic partner).

1.	Do you have a financial arrangement with the sponsor, whereby the value of compensation could be influenced by the outcome of the research? This includes compensation that could be greater for a favorable clinical result, compensation in the form of an equity interest in the sponsor, or compensation tied to sales of the product or service being tested (e.g., royalty interest).	☒ No ☐ Yes
2.	Do you have a proprietary interest in the product or service being tested such as patent rights, trademark, copyright or licensing agreement?	☒ No ☐ Yes
3.	Do you have a significant equity interest in the sponsor or in the product or service being tested (e.g., ownership interest, stock options, or any other financial interest) the value of which cannot be readily determined through reference to public prices, any equity interest in the sponsor (if publicly traded) exceeding $10,000 (**or $5,000 for PHS-funded research**), or more than 5% ownership (or any combination of these), in the sponsoring company or business entity?	☒ No ☐ Yes
4.	Have you received payments from the sponsor or payments related to the product or service being tested in excess of $10,000 (**or $5,000 for PHS-funded research**), when aggregated for immediate family members, exclusive of the costs of conducting the research, such as honoraria, a grant or grants to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation?	☒ No ☐ Yes
5.	Have you accepted payment arrangements from the sponsor such as financial incentives for early enrollment or high enrollment (e.g., recruitment bonus incentives)?	☒ No ☐ Yes
6.	Do you have any board or executive relationship to the sponsor or the product or service being tested, regardless of the compensation?	☒ No ☐ Yes
7.	Are you an employee of the sponsor or the manufacturer of the test article?	☒ No ☐ Yes
8.	Do any of the research staff or their immediate family members have financial or other COIs with the sponsor conducting this research, the test article, or the manufacturer of the test article, as listed above? Salus IRB defines "research staff" as anyone responsible for the design, conduct, or reporting of research (e.g., sub-investigators, research coordinators).	☒ No ☐ Yes

If you answered "Yes" to any of the questions above, **describe the COI(s) in detail** and explain how the COI(s) will be managed so that the conflict(s) will not adversely affect the protection of participants or the integrity of the research (notification of the existence of a COI and how it will be managed may be added to the ICD):

Salus IRB

PROTOCOL SPECIFIC INVESTIGATOR AND SITE RESOURCES

Sciences Inc.

SPONSOR: Guardion Health **PROTOCOL #:** ~~LumegaZ Protocol~~ 1

INVESTIGATOR: Thomas Henderson, MD JT 31 Oct 17

CERTIFICATION STATEMENT AND SIGNATURE:

I certify that the information provided within this application is true and accurate to the best of my knowledge, and represents my intent to pursue review of this research by Salus IRB. My signature below indicates that:

- ☒ *I have reviewed the Investigator Reporting Responsibilities and the Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information. [Click hyperlink(s) above].*
- ☒ *If study staff/sub-investigators are permitted to sign research documents in lieu of the PI, I understand it is my responsibility to ensure that the delegated staff are notified of the reporting requirements;*
- ☒ *I understand I may contact Salus IRB at any time with questions or concerns about these requirements;*
- ☐ *I agree to conduct the study in accordance with my responsibilities as a PI, applicable regulations, Good Clinical Practices and the determinations of Salus IRB;*
- ☒ *I understand that it is my obligation to review the Investigator's Statement of Agreement on Form 110.A;*
- ☒ *I attest that the information submitted to Salus IRB on Form 110.A – Investigator and Site Information signed by me on* 10/26/17 *is true and accurate.*

By signing this form, I grant Salus IRB the authority to approve and oversee the above referenced research and certify that the study will not begin until I have received Salus IRB approval of the FINAL protocol and ICD. Further, I understand that only the Salus IRB-approved ICD may be used to enroll participants.

Thomas Henderson, MD
Printed Name of Investigator

Thenderson MD
Signature of Investigator

10/26/17
Date

LIST OF ATTACHMENTS:

REQUIRED DOCUMENTS:

- ☒ Completed and signed *Protocol Specific PI and Site Resources Form* (this document)
- ☐ The sub-investigator's (performing procedures the PI is not qualified and licensed to perform) current CV and professional license, if applicable. This will be saved in our investigator files for future reference.
- ☐ **Attached explanation for any question answered "Yes" that requires an attachment**

For Recruitment and Study Material: Please forward the **Microsoft Word version of each file** requiring review. Include the **document title** and **version (number or date)** in each file.

- ☐ All proposed study material (diaries, survey instruments, or questionnaires)
- ☐ All proposed recruitment material (audio/video script, print advertisement)

October 27, 2017

Salus IRB Form 100 Initial Review (Protocol)

Section D – Description

The ICD clearly states additional costs: You do not have to pay for the specific study supplements. Since these same tests would be conducted as part of the routine care for macular degeneration, they would be submitted to your insurance plan and you will be responsible as usual, for expenses under deductibles and copays.

LUMEGA-Z

Ingredients

Serving Size: 0.75 FL. OZ. (1.5 Tbsp) — Servings Per Container: 7

	Amout Per Serving 0.75 FL. OZ.	% Daily Value
Calories	10	
Vitamin C (as ascorbic acid and calcium ascorbate)	500 mg	833%
Vitamin D3 (as cholecalciferolin MCT)	2000 IU	500%
Vitamin E (as mixed tocopherols with not less than 50 mg of gamma tocopherol)	200 IU	665%
Thiamin (vitamin B1 as thiamin HCl)	1.5 mg	100%
Riboflavin	1.7 mg	100%
Niacin (as niacinamide)	20 mg	100%
Vitamin B6 (as pyridoxine HCl)	10 mg	500%
Folate (as folic acid)	800 mcg	200%
Vitamin B12 (as methylcobalamin)	1000 mcg	16,667%
Biotin	100 mcg	33%
Pantothenic Acid (as d-calcium pantothenate)	10 mg	100%
Calcium (as calcium lactate gluconate)	250 mg	25%
Magnesium (as magnesium citrate)	100 mg	25%
Zinc (as zinc amino acid chelate)	25 mg	167%
Selenium (as selenium sodium selenate)	70 mcg	100%
Copper (as copper gluconate)	2 mg	100%
Manganese (as manganese gluconate)	2 mg	100%
Chromium (as chromium picolinate)	120 mcg	100%
Molybdenum (glycinate chelate)	75 mcg	100%
NAC (N-acetyl-cysteine)	500 mg	*
Acetyl-L-Carnitine	500 mg	*
L-Taurine	500 mg	*
Quercetin	100 mg	*
CoQ10 (as ubiquinone)	50 mg	*
Lutein**	15 mg	*
Meso-zeaxanthin**	10 mg	*
Zeaxanthin**	3 mg	*
Astaxanthin	1000 mcg	*
Lycopene	500 mcg	*
Proprietary Ocular Antioxidant Blend (bilberry fruit extract 4:1, alpha-lipoic acid)	200 mg	

* Daily value not established.

Other Ingredients: Purified water, vegetable glycerin, polysorbate 80, acacia gum, soybean lecithin, malic acid, natural flavors, sucralose, potassium sorbate, sodium benzoate, medium chain triglycerides.

Contains ***Nutri-Mz* and sold subject to US patents 6,218,436 and 6,329,432 and others worldwide.

NO sugar, yeast, gluten, or dairy.

Omega *Boost*

Ingredient Facts

Serving Size: 2 Soft Gels — Servings Per Container: 30

	Amout Per Serving	% Daily Value*
Calories	10	
Calories from Fat	10	
Total Fat	1.5 g	2%
Saturated Fat	0 g	0%
Polyunsaturated Fat	1 g	†
Monounsaturated Fat	0 g	†
Fish Oil Concentrate	1260 mg	†
DHA (docosahexaenoic acid)	620 mg	†
EPA (eicosapentaenoic acid)	160 mg	†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily value not established.

Ingredients: Alaska Walleye Pollock *(theragra chalcogramma)*, gelatin, glycerin, purified water, mixed natural tocopherols.

NO gluten, dairy, or artificial colors or flavors.

Each 4-week supply includes:
4 bottles x 5.25 Fl. Oz.
Lumega-Z Medical Food
With 60 Omega Boost Soft Gels

LUMEGA-Z®
Advanced Ocular Health
Medical Food

The Medical Food created to restore and maintain the Macular Pigment

LUMEGA-Z
Advanced Ocular Health
Medical Food

Contains all three macular carotenoids:
Lutein
Zeaxanthin
Meso-zeaxanthin

To order LUMEGA-Z, go online at:
www.lumegaz.com
or call (800) 873-5141

as well as a robust complex of critical Micronutrients and Omega 3's

GUARDION® HEALTH SCIENCES
The Macular Pigment Specialists

Formulated and distributed by:
Guardion Health Sciences, Inc.
San Diego, California

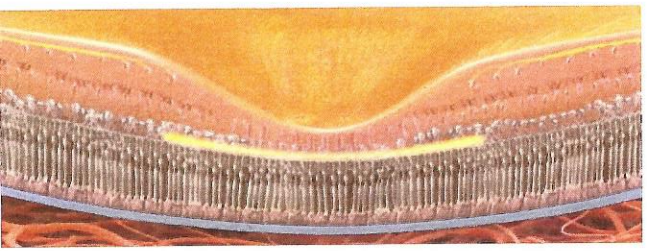
Made in the U.S.A.

Patent Pending

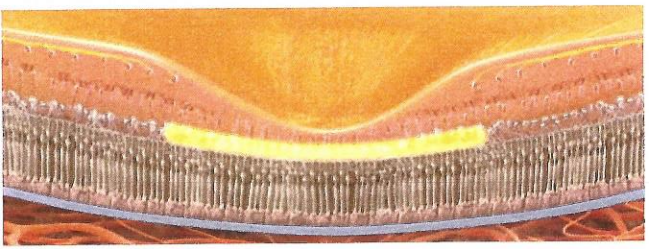
What is Lumega-Z?

Lumega-Z is a medical food created to restore and maintain the macular protective pigment.

Macular pigment protects the macula (the part of your retina responsible for sharp, central vision) against oxidative stress, free radicals, and damaging blue light.



Example of a depleted macular pigment

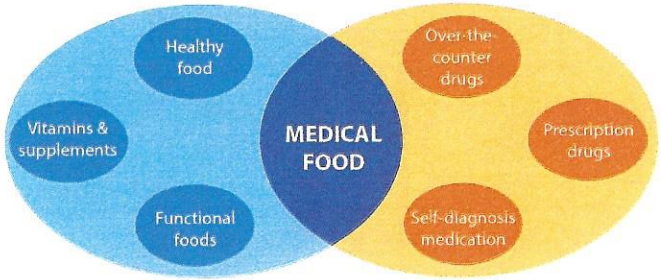


Example of a restored macular pigment

A depleted macular pigment is a known high risk factor for age-related macular degeneration and other retinal diseases.

What is Medical Food?

A Medical Food is not a drug. It is not a supplement either.



Medical foods are a regulated category of product "… formulated to be consumed or administered… under the supervision of a professional healthcare provider and intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

(Per Section 5(b) of the Orphan Drug Act)

LUMEGA-Z®

Advanced Ocular Health Medical Food

Restores and maintains a depleted macular pigment

Decreases glare and light sensitivity

Liquid formula is easy to swallow and digest

Promotes overall ocular health

Can replace your daily multivitamin

Able to be purchased with Healthcare Flexible Spending Account (FSA)

Tax-deductible as a medical expense

All research and scientific data is available upon request.

PreserVision AREDS 2 Formula Eye Vitamins for AMD

Thomas Henderson MD

Thu 10/26/2017 11:32 PM

To:Valerie Gatavaski <vgatavaski@eyeclinicofaustin.com>;

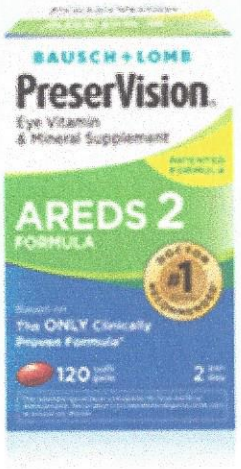
Cc:Thomas Henderson MD <thenderson@eyeclinicofaustin.com>;

Sunday, October 15, 2017
4:26 PM

PreserVision AREDS 2 Formula

PreserVision AREDS 2 Formula builds on the original, clinically proven ***PreserVision*** AREDS Formula, with lutein and zeaxanthin replacing beta-carotene, based on the AREDS2 study.*

PreserVision AREDS 2 Formula exactly matches the nutrient formula recommended by the AMD experts at the National Eye Institute based on the AREDS2 study.



National Eye Institute Recommended Formula:

Nutrient	Amount (per day)	Percent Daily Value*
Vitamin C	500 mg	840%
Vitamin E	400 IU	1340%

Zinc	80 mg	540%
Copper	2 mg	100%
Lutein	10 mg	**
Zeaxanthin	2 mg	**

*Percent Daily Values (DV) based on a 2,000-calorie diet

**Daily Value (DV) not established

Speak with your doctor to determine if the updated AREDS 2 formula is right for you.

PreserVision AREDS 2 formula exactly matches the levels of clinically proven nutrients recommended by the National Eye Institute based on the AREDS2 study.

PreserVision AREDS 2 Formula Eye Vitamins for AMD

http://www.preservision.com/products/preservision-areds-2-formula

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4823 Gerona Drive
Austin, Texas 78759
(512) 372-6216 Hm

CURRICULUM VITAE

Thomas T. Henderson, M.D., F.A.C.S.

Current Position:
President and Chief Executive Officer
Eye Clinic of Austin, PLLC Thomas Henderson Sole Mbr

Business Address:
Eye Clinic of Austin
3410 Far West Boulevard, Suite 140
Austin, Texas 78731

Business Phone:
(512) 427-1100 Main
(512) 427-1207 Main Fax

Web Address / Electronic Mail:
www.eyeclinic2020.com
thenderson@eyeclinic2020.com

Birthdate:
January 12, 1947

Birthplace:
Wichita, Kansas

Licensure & Certifications:
Physician Permit, Texas F4863
June 13, 1979 to Present
Medicine & Surgery, Virginia 0101026396
December 6, 1975 to Present
American Board of Ophthalmology
Written exam, passed 98th percentile, January 1980
Oral exam, passed, October 1980
National Board of Medical Examiners
Passed, 1973
American College of Surgeons – Fellow
Certified, October 1997

Education & Internships:
Medical Doctor
University of Texas
Southwestern Medical School
Dallas, Texas
1969 to 1973

Bachelor of Science, Psychology
Louisiana State University
1965 to 1969

Surgery Externship
Presbyterian Hospital
Dallas, Texas
1971

OB/GYN Externship
Parkland Memorial Hospital
Dallas, Texas
1972

Rotating Internship
San Francisco General Hospital Medical Center
San Francisco, California
1973 to 1974

Residency in Ophthalmology
Baylor College of Medicine
Houston, Texas
1976 to 1979

Post Graduate Medical Experience:

Lieutenant Commander
U.S. Public Health Service, Commissioned Corps
General Medical Officer
Norfolk, Virginia 1974 to 1975
Galveston, Texas 1975 to 1976

Ophthalmology Practice Experience:
Private Practice:

Thomas Henderson, M.D., P.A., d.b.a.
Eye Clinic of Austin
3410 Far West Boulevard, Suite 140 Austin, Texas 78731
December 1990 to Present
900 East 30th Street, Suite 200 Austin, Texas 78705
January 1982 to December 1990

Medical Center Eye Associates
Houston, Texas
August 1980 to December 1981

Rugley-Blasingame Clinic
Wharton, Texas
July 1979 to May 1980

Voluntary Clinical Faculty:

Supervision of Resident Surgical Cases
Baylor College of Medicine
Department of Ophthalmology

Houston, Texas
1980 to 1981

Hospital Affiliations:

Northwest Hills Surgical Hospital (formerly HealthSouth)
Austin, Texas
Chief of Staff, 1995 to 2003
1995 to Present

Texan Surgery Center
Austin, Texas
2004 to Present

Austin Diagnostic Clinic
Ambulatory Surgery Center – Lakewood
Austin, Texas
2005 to Present

The Hospital at Westlake Medical Center
Austin, Texas
2006 to Present

Academy of Laser Vision Sciences
Austin, Texas
2003 to Present

Seton Health Care

Brackenridge Hospital
Seton Medical Center
Seton Northwest Hospital
Dell Children's Hospital of Austin
Austin, Texas 1982 to Present

St. David's Healthcare Partnership

St. David's Medical Center*
South Austin Hospital
Bailey Square Surgery Center 2005 to Present
Austin, Texas 1982 to Present
*Chief of Ophthalmology 1997 to 1999
*Chief of Operations 1988 to 1990

Previous Affiliations:

Park Plaza Hospital – Houston, Texas 1990 to 1991
Austin Surgical Center – Austin, Texas 1986 to 1995
Harris County Hospital – Houston, Texas 1980 to 1981
Twelve Oaks Hospital – Houston, Texas 1980 to 1981
Polly Ryan Memorial – Richmond, Texas 1979 to 1980
Gulf Coast Medical Ctr – Wharton, Texas 1979 to 1980
Caney Valley Memorial – Wharton, Texas 1979 to 1980

Honors & Awards:

Austin HealthCare Hero Nominee 2009
Best Doctors in America, 1996 to 2012
Texas Super Doctor, 2005, 2006, 2008, 2009, 2011 & 2012
Guide to America's Top Ophthalmologists 2006, 2009, 2010, 2011 & 2012
LaserVision's® Top 100 Surgeons 2008
Austin Top Refractive Eye Surgeons 2008
Consumers' Guide to Top Doctors 2003
Southwestern Medical School Class Rank #1 in senior year, 26/105 overall
Louisiana State University – Phi Kappa Phi (National Honor Society)

Professional Organizations:

American Academy of Ophthalmology
Texas Ophthalmological Association
Austin Ophthalmological Society (1993, President)
American Society of Cataract and Refractive Surgery
International Society of Refractive Surgery of A.A.O.
American Medical Association
Texas Medical Association
Travis County Medical Society
American College of Eye Surgeons
American College of Surgeons
Contact Lens Association of Ophthalmologists

Teaching Experience:

Cedar Creek Elementary School
Austin, Texas
Lecturer "Dangers of Children's Ballgames"
March 1982

Texas Society to Prevent Blindness
Austin, Texas
Public Service Representative – Two radio broadcasts
July 1981

University of Houston, College of Optometry
Houston, Texas
Lecturer "Preventable Blindness Sub-Retinal Neo Vascular Membranes" April 1981

Ben Taub Hospital
Houston, Texas
Instructor – Resident Surgery/Ophthalmology
1980 to 1981

Gulf Coast Medical Center
Wharton, Texas
Lecturer "Sarcoid and the Eye"
Clinical 1979

Baylor College of Medicine
Houston, Texas Ophthalmic Assistants Program:
Instructor "Light, Form & Color" & "Optics & Refraction"
1977 to 1978

Clinical Studies:

- Allergan, ISOP-101-8702, Sub-Investigator
- Ciba Giegey Protocol 19684A, Primary
- Pharmaco, RG121561, Sub-Investigator
- Organon, Birth Control, Sub-Investigator
- Insite Vision Pilasite/Pilopine, Primary
- Merck, Sharpe & Dohme MK507 Compassionate
- Pharmacia, Xalatan, Open Label
- Alcon, Timolol, Triple Masked
- Alcon, Olopatadine QD, November 2001
- Alcon, Blepharitis, Ciprodex, 2002 to 2003
- Alcon, Brimonidine Tartarte Generic 2003 to 2004
- Otsuka, Dry Eye Study 2004 to 2006 Primary
- Insite Vision, C-04-35 Allergic Conjunctivitis 2004
- Alcon, Allergic Conjunctivitis, Olopatadine 2004-05
- Novartis CASM981E2205, Dry Eye 2004-05
- Bausch & Lomb 433 Bacterial Conjunctivitis 2006
- Alcon, C-07-40 – Phase 3 Blepharitis 2008-2009
- Alcon, C-08-47 – Travatan-Z 2008-2009
- Inspire Pharmaceuticals, 03-113 Dry Eye 2009
- Inspire Pharmaceuticals, 044-101 Blepharitis 2009
- Alcon, C-09-034 – Allergic Conjunctivitis 2010
- Fovea Pharmaceutical's Fov 1101-11 2010

Continuing Education:

- American Academy of Ophthalmology
  Focal Points 1995 (Reading Assignment)
  January 29, 1996
  Category 1, Hours: 15.0

- Presbyterian Hospital – Dallas, TX
  18th Annual Spring Ophthalmology Symposium
  The Business of Success
  March 8, 1996
  Category 1, Hours: 7.0

- Texas Medical Association – Austin, TX
  Witness for the Defendant Physician
  May 10, 1996

Category 1, Hours: 3.0

- Texas Medical Association – Austin, TX
  Texas Ophthalmology Association Refractive Symposium
  May 11, 1996
  Category 1, Hours: 3.5

- Texas Medical Association – Austin, TX
  Legislative Workshop
  May 11, 1996
  Category 1, Hours: 2.0

- Texas Medical Association – Austin, TX
  OMIC Workshop
  May 11, 1996
  Category 1, Hours: 3.0

- Baylor College of Medicine – Houston, TX
  Baylor Welsh Cataract & Refractive Surgical Congress
  September 5 – 7, 1996
  Category 1, Hours: 20.0

- American Academy of Ophthalmology – Chicago, IL
  Annual Meeting: VISX PRK Course & Lab
  October 25-27, 1996 through November 1997
  Category 1, Hours: 16.0

- American Academy of Ophthalmology – Chicago, IL
  Annual Meeting: Reshaping the Future: Refractive Surgery
  October 25-27, 1996
  Category 1, Hours: 12.0

- American Academy of Ophthalmology – Chicago, IL
  1996 Annual Meeting
  October 31, 1996
  Category 1, Hours: 16.0

- American Academy of Ophthalmology
  Focal Points 1996 (Reading Assignment)
  January 8, 1997
  Category 1, Hours: 15.0

- Scott and White Memorial Hospital – Temple, TX

Everett R. Veirs Lecture & Ophthalmology Conference
February 21-22, 1997
Category 1, Hours: 8.0

- Presbyterian Hospital – Dallas, TX
  19th Annual Spring Ophthalmology Symposium
  Resurfacing the Future
  March 14, 1997
  Category 1, Hours: 7.0

- American Academy of Ophthalmology and
  Texas Ophthalmology Association – Dallas, TX
  CodeQuest Ophthalmic Coding College 1997:
  Coding, Documentation & Compliance Seminar
  March 15, 1997
  Category 1, Hours: 7.0

- American Society of Cataract & Refractive Surgery
  & American Society of Ophthalmic Administrators –
  Boston, MA
  Symposium on Cataract, IOL & Refractive Surgery
  April 26-30, 1997
  Category 1, Hours: 40.0

- St. David's Hospital – Austin, TX
  St. David's Grand Rounds; Treatment for Chronic
  Pain Syndrome
  July 18, 1997
  Category 1, Hours: 1.0

- Presbyterian Hospital – Dallas, TX
  Cataract 1997
  September 12, 1997
  Category 1, Hours: 7.0

- Barnet Dulaney Eye Foundation – San Antonio, TX
  Advanced Concepts in Phacoemulsification
  September 20, 1997
  Category 1, Hours: 6.5

- Barnet Dulaney Eye Foundation – San Antonio, TX
  Refractive Update: Techniques, Technology &
  Results
  September 20, 1997
  Category 1, Hours: 4.5

- LaserVision Centers, Inc. – Austin, TX
  Laser In-Sita Keratomileusis Fellowship Program
  LASIK Study Group
  October 11-12, 1997

- Bausch & Lomb – Austin, TX
  C-LASIK Course
  October 11-12, 1997

- American College of Surgeons – Chicago, IL
  Clinical Congress 1997
  October 12-17, 1997
  Category 1, Hours: 3.0

- American Academy of Ophthalmology –
  San Francisco, CA
  Reshaping the Future – Refractive Surgery
  October 25, 1997
  Category 1, Hours: 13.0

- American Academy of Ophthalmology –
  San Francisco, CA
  Subspecialty Day 1997 – Scientific Exhibits & Programs
  October 26, 1997
  Informal, Hours: 9.0

- American Academy of Ophthalmology -
  San Francisco, CA
  Current Concepts in the Management of Glaucoma
  October 26, 1997
  Category 1, Hours: 1.0

- American Academy of Ophthalmology
  Focal Points 1997 (Reading Assignment)
  January 12, 1998
  Category 1, Hours: 15.0

- American Heart Association
  Advanced Cardiac Life Support
  March 11, 1998

- American Management Association
  How to Get More Organized

March 19, 1998

- Excerpta Medical Office of Continuing Medical Education
  Open Angle Glaucoma: A Focus on Current Management
  April 14, 1998
  Category 1, Hours: 2.0

- Johns Hopkins University School of Medicine
  Office of Continuing Medical Education
  Hopkins Business of Medicine Executive Medical Business Certificate;
  Managed Care: Perspectives & Practices
  April 8, 1998 to June 10, 1998
  Category 1, Hours: 30.0

- Johns Hopkins University School of Medicine
  Office of Continuing Medical Education
  Hopkins Business of Medicine Executive Medical Business Certificate;
  Accounting for Decision Making in Medicine
  September 9, 1998 to November 18, 1998
  Category 1, Hours: 30.0

- Johns Hopkins University School of Medicine
  Office of Continuing Medical Education
  Hopkins Business of Medicine Executive Medical Business Certificate;
  Managerial Finance for Medical Services
  February 22, 1999 to April 26, 1999
  Category 1, Hours: 30.0

- St. David's Medical Center – Austin, TX
  St. David's Grand Rounds; Antibiotic Update
  March 2, 1999
  Category 1, Hours: 1.0

- Johns Hopkins University School of Medicine
  Office of Continuing Medical Education
  Hopkins Business of Medicine Executive Medical Business Certificate;
  Leadership & Organizational Behavior in Medical Settings
  May 3, 1999 to July 12, 1999
  Category 1, Hours: 30.0

- American Academy of Ophthalmology
  Refractive Subspecialty Day 1999:
  Scientific Exhibits & Programs
  October 22-23, 1999
  Informal, Hours: 9.0

- SLACK, Inc. – Dallas, TX
  Selective Laser Trabeculotherapy:
  An Innovative Treatment for Glaucoma
  October 24, 1999
  Category 1, Hours: 2.5

- The Barnet Dulaney Eye Foundation –
  San Antonio, TX
  Advanced Concepts in Cataract & Refractive Surgeries
  September 9, 2000
  Category 1, Hours: 7.0

- The Barnet Dulaney Eye Foundation –
  San Antonio, TX
  Refractive Update
  September 10, 2000
  Category 1, Hours: 4.0

- Medical Education Collaborative – Dallas, TX
  New Advances in Ophthalmic Fluroquinolones
  October 21, 2000
  Category 1, Hours: 1.5

- The University of Texas – Houston Medical School
  Houston, TX
  Vision 2001 Spring Meeting
  March 24, 2001
  Category 1, Hours: 8.0

- The University of Texas – Health Science Center
  San Antonio, TX
  New Treatment Paradigms in the Management of Glaucoma
  May 18-19, 2001
  Category 1, Hours: 3.75

- The University of Texas – Southwestern Medical

School – Dallas, TX
Ophthalmology Update: 20th Anniversary Seminar
September 8, 2001
Category 1, Hours: 7.0

- SLACK, Inc. – Dallas, TX
  Three Targets for Glaucoma Management:
  A New Approach
  April 13, 2002
  Category 1, Hours: 3.5

- The Delaney Foundation – San Antonio, TX
  Advanced Excellence in LASIK
  May 5, 2002
  Category 1, Hours: 5.0

- The University of Texas – Southwestern Medical School – Dallas, TX
  Clinical Applications of Ocular Bloodflow in Glaucoma & Age-Related Macular Degeneration
  October 5, 2002
  Category 1, Hours: 4.5

- The University of Texas – Medical Branch
  Galveston, TX
  Office of Continuing Education
  Medical Therapy of Glaucoma 2002:
  Prostoglandins and More
  October 10, 2002
  Category 1, Hours: 1.0

- Seton HealthCare Network – Austin, TX
  Brain & Spine Center at Brackenridge
  Current Concepts in Stroke
  November 16, 2002
  Category 1, Hours: 7.0

- Primary Care Network, Inc. – Houston, TX
  The Headache Patient: Practical Strategies for Diagnosis and Treatment
  November 23, 2002
  Category 1, Hours: 4.0

- Lumenis – San Antonio, TX
  Selective Laser Trabeculoplasty:
  The Latest Advance in Glaucoma Therapy

November 21, 2002
Informal

- St. David's Medical Center – Austin, TX
  St. David's Grand Rounds 2003:
  Documentation – First Line Malpractice Defense
  January 7, 2003
  Category 1, Hours: 1.0

- Primary Care Network, Inc. – Austin, TX
  Asthma: A Comprehensive Approach to Detection & Management
  March 1, 2003
  Category 1, Hours: 4.0

- The Dulaney Foundation – Austin, TX
  Ocular Allergy: New Concepts in Therapy
  March 20, 2003
  Category 1, Hours: 1.0

- Scott and White Memorial Hospital – Temple, TX
  Everett R. Veirs Lecture & Ophthalmology Conference
  April 26, 2003
  Category 1, Hours: 7.0

- SLACK, Inc. – Las Vegas, NV
  1st Annual Ocular Surgery News Symposium
  Glaucoma: Improving Your Odds
  June 6-7, 2003
  Category 1, Hours: 11.0

- Texas Medical Liability Trust – Austin, TX
  Don't Make Me Sue You
  June 27, 2003
  Category 1, Hours: 1.0
  Ethics, Hours: 1.0

- Boron Lepore
  Applying the Data to Contemporary Clinical Practice: Managing Elevated Intraocular Pressure
  June 30, 2003
  Informal, Hours: 1.0

- The Dulaney Foundation – Austin, TX
  Fluroquinolone Update

July 22, 2003
Category 1, Hours: 1.0

- National Association of Managed Care Physicians
  Immune Based Dry Eye: A Progressive Disease
  August 2003
  Category 1, Hours: 1.0

- The Dulaney Foundation – San Antonio, TX
  New and Emerging Techniques & Technology in Cataract & Refractive Surgery
  September 13, 2003
  Category 1, Hours: 11.0

- The Dulaney Foundation – Austin, TX
  Procedures for the Glaucoma Patient
  September 18, 2003
  Category 1, Hours: 1.0

- Texas Medical Liability Trust – Austin, TX
  Medical Errors, Mandatory Disclosure & You
  November 18, 2003
  Category 1, Hours: 3.0
  Ethics, Hours: 1.0

- VISX – Austin, TX
  Physician CustomVue Certification Course
  November 23, 2003
  Certification

- Bausch & Lomb Surgical – Austin, TX
  Technolas 217A Laser Training
  September 11, 2003
  Certification

- Primary Care Network – Austin, TX
  Evidence-Based Medicine: A Framework for Clinical Practice
  February 7, 2004
  Category 1, Hours: 4.0

- American Medical Association – Austin, TX
  Depression in Primary Care
  February 20, 2004
  Informal, Hours: 1.0

- Texas Medical Association – Austin, TX
  Defensive Documentation Austin
  February 24, 2004
  Category 1, Hours: 3.0
  Ethics, Hours: 3.0

- Alcon & The AOS – Austin, TX
  Allergy/Dry Eye Update
  March 11, 2004
  Informal, Hours: 2.0

- Texas Medical Association – Austin, TX
  E&M Documentation
  March 16, 2004
  Category 1, Hours: 3.0
  Ethics, Hours: 1.0

- Pfizer – Austin, TX
  Interactive Roundtable Discussion on the Management of Glaucoma
  March 31, 2004
  Informal, Hours: 1.0

- Alcon Laboratories, Inc. – Naples, FL
  Glaucoma Advisory Summit
  April 2 – 4, 2004
  Informal, Hours: 8.0

- Maryland Research Institute – Cancun, Mexico
  Otsuka Dry Eye Study Coordination Conference
  PPD Development
  April 19 – 21, 2004
  Informal, Hours: 8.0

- The Dulaney Foundation – Austin, TX
  Blue Light and IOL Designs
  April 26, 2004
  Category 1, Hours: 1.0

- Scott and White Memorial Hospital – Temple, TX
  Everett R. Veirs Lecture & Ophthalmology Conference
  May 1, 2004
  Category 1, Hours: 6.0

- Texas Medical Association – Austin, TX
  TexMed 2004 – Ophthalmology Day 2
  May 15, 2004
  Category 1, Hours: 7.0
  Ethics, Hours: 3.0

- Ophthalmology Update – Austin, TX
  Glaucoma Management: IOP Lowering Agents
  June 9, 2004
  Category 1, Hours: 1.0

- University of Florida – Austin, TX
  The Emerging Role for Neuroprotection in the Management of Glaucomatous Optic Neuropathy
  June 15, 2004
  Category 1, Hours: 0.5

- Novartis Ophthalmics – Austin, TX
  AMD: The Fight for Sight
  June 24, 2004
  Informal, Hours: 1.0

- Allergan – Austin, TX
  Teleconference: Restasis
  July 21, 2004
  Informal, Hours: 1.0

- The Dulaney Foundation – Austin, TX
  LASIK Flap Complications: The next step in prevention and management
  July 22, 2004
  Category 1, Hours: 1.0

- Interactive Information Solutions – Austin, TX
  Corneal Wound Healing: A Review of ARVO 2004 Abstracts
  July 29, 2004
  Category 1, Hours: 1.0

- Inspire Pharmaceuticals – Austin, TX
  A New Multiaction Therapy for Itch Associated with Allergic Conjunctivitis
  August 12, 2004
  Informal, Hours: 1.0

- Alcon Laboratories, Inc. – San Antonio, TX
  Ophthalmic Symposium: Advances in Anterior Segment Surgery
  August 28, 29, 2004
  Category 1, Hours: 4.0

- Postgraduate Institute for Medicine – Austin, TX
  Cystoid Macular Edema: New Dynamics for Prophylaxis and Treatment
  September 8, 2004
  Category 1, Hours: 1.0

- Austin Ophthalmology Society – Austin, TX
  Pfizer Ophthalmics
  Update on the Management of Glaucoma
  September 9, 2004
  Informal, Hours: 1.0

- The New York Eye and Ear Infirmary Institute for Continuing Medical Education–New Orleans, LA
  Winds of Change: A Evidence-Based Approach
  October 22, 2004
  Category, 1, Hours: 1.5

- The New York Eye and Ear Infirmary Institute for Continuing Medical Education-New Orleans, LA
  Forge: Focusing Ophthalmology on Reframing Glaucoma Evaluation
  October 23, 2004
  Category 1, Hours: 1.5

- The New York Eye and Ear Infirmary Institute for Continuing Medical Education-New Orleans, LA
  What's New in Retinal Imaging: What Every Comprehensive Ophthalmologist Needs to Know
  October 24, 2004
  Category 1, Hours: 1.5

- VISX – Austin, TX
  VISX Fourier Wavefront Upgrade a CustomVue Technology
  October 28, 2004
  Informal, Hours: 1.0

- Texas Medical Association – Austin, TX
  Hallway Consultations & Professional Courtesy
  November 18, 2004
  Category 1, Hours: 3.0
  Ethics, Hours: 3.0

- The Dulaney Foundation – Las Vegas, NV
  Refractive IOL Symposium
  December 4-5, 2004
  Category 1, Hours: 11.0

- VISX – Houston, TX
  CustomVue VISX Technology Update
  February 16, 2005
  Informal, Hours: 3.0

- American Academy of Ophthalmology and
  Texas Ophthalmology Association – Austin, TX
  CodeQuest Ophthalmic Coding College 2005:
  Coding, Documentation & Compliance Seminar
  March 5, 2005
  Category 1, Hours: 6.0

- The Dulaney Foundation – Austin, TX
  Glaucoma 2005
  March 10, 2005
  Category 1, Hours: 1.0

- Texas Health Research Institute – Dallas, TX
  27th Annual Spring Ophthalmology Symposium
  April 1, 2005
  Category 1, Hours: 7.0

- Neuroscience – Dallas, TX
  Link between Neurotransmitters and Hormones
  April 2, 2005
  Category 1, Hours: 4.0

- The Dulaney Foundation – Fort Worth, TX
  Apodized Diffractive Lens Symposium
  April 9, 2005
  Category 1, Hours: 5.0

- SLACK, Inc. – Houston, TX
  Update on the Management of Diabetic
  Retinopathy and its Complications

April 16, 2005
Category 1, Hours: 4.0

- The Dulaney Foundation – San Antonio, TX
  Allergy Update
  April 18, 2005
  Category 1, Hours: 1.0

- Price Vision Group – Indianapolis, IN
  Advanced Cornea Course
  April 26 & 27, 2005
  Category 1, Hours: 13.0

- National Association of Managed Care Physicians – Austin, TX
  Emerging Trends in the Successful Diagnosis and Treatment of Chronic Dry Eye Disease
  May 17, 2005
  Category 1, Hours: 1.0

- The Dulaney Foundation – Dallas, TX
  Revolutions in Cataract Business &Marketing
  May 22, 2005
  Category 1, Hours: 3.0

- Advanced Medial Optics, Inc. – Austin, TX
  ReZoom Multifocal IOL
  July 1, 2005
  Certification

- The Dulaney Foundation – San Antonio, TX
  Ophthalmic Symposium
  August 26-28, 2005
  Category 1, Hours: 7.5

- The Dulaney Foundation – Austin, TX
  Allergy and Dry Eye Update
  September 15, 2005
  Category 1, Hours: 1.0

- Scott and White Memorial Hospital – Temple, TX
  Everett R. Veirs Lecture & Ophthalmology Conference
  October 1, 2005
  Category 1, Hours: 7.0

- American Academy of Ophthalmology – Chicago, IL
  AAO Conference: Subspecialty & Annual Meeting
  October 14-18, 2005
  Category 1, Hours: 17.0

- The Dulaney Foundation – Chicago, IL
  Phaco and Refractive Pearls From Around the World
  October 15, 2005
  Category 1, Hours: 3.0

- Optos – Chicago, IL
  Optos Academy Workshop
  Informal, Hours: 1.5

- ASCRS – Chicago, IL
  Redefining Lenticular Refractive Surgery
  October 17, 2005
  Category 1, Hours: 1.5

- Texas Medical Association – Austin, TX
  Coordination of Care 2005
  October 18, 2005
  Category 1, Hours: 3.0
  Ethics, Hours: 3.0

- Medical Education Collaborative – Austin, TX
  Managing the Risk of Intravitreal Injections
  October 27, 2005
  Category 1, Hours: 1.5

- Neuroscience – San Antonio, TX
  Neurotransmitters and Adrenal Stress
  February 7, 2006
  Category 1, Hours: 5.0

- Allergan – Houston, TX
  Dry Eye Speaker Bureau Update Meeting
  March 3-5, 2006
  Informal, Hours: 12.0

- ASCRS – San Francisco, CA
  March 17-22, 2006
  Informal, Hours: 20.0

- Texas Health Resources – Dallas, TX

The 28th Annual Spring Ophthalmology Symposium
March 24, 2006
Category 1, Hours: 7.0

- Texas Medical Association – Austin, TX
  Retina Case Conundrums
  May 25, 2006
  Category 1, Hours: 1.0

- Neuroscience – Dallas, TX
  Neurochemical and Hormonal Consequences of the Modern Lifestyle: Avenues to Overcome the Resulting Imbalances
  June 17, 2006
  Category 1, Hours: 7.0

- Center for Accredited Healthcare Education
  Austin, TX
  Retinopathy Reporter: An Expert Dialogue on Diabetic Retinopathy Spring 2006 Issue
  June 23, 2006
  Category 1, Hours: 0.75

- Neuroscience – Austin, TX
  ADHD: Attention, Hyperactivity & the Adrenal Gland
  July 12, 2006

- Neuroscience – Austin, TX
  PMS, Menopause and Dysmenorrhea: Looking Beyond Hormones
  July 26, 2006

- The Dulaney Foundation – San Antonio, TX
  Advances in Anterior Segment & Refractive Surgery
  August 26 & 27, 2006
  Category 1, Hours: 11.0

- Hawaiian Eye 2007 – Kauai, HI
  January 13-19, 2007
  Category 1, Hours: 34.5

- Texas Medical Association – Austin, TX
  Verdict 2007
  March 8, 2007
  Category 1, Hours: 3.0

Ethics, Hours: 3.0

- Texas Medical Association – Austin, TX
  Retina Case Conundrums III 2007
  April 12, 2007
  Category 1, Hours: 2.0

- The Dulaney Foundation – Austin, TX
  Ocular Allergy: Treatment Goals and
  Therapeutic Evaluation
  April 19, 2007
  Category 1, Hours: 1.0

- The Dulaney Foundation – Austin, TX
  Innovations in Glaucoma Therapy
  May 10, 2007
  Category 1, Hours: 1.0

- Texas Medical Foundation – Austin, TX
  Electronic Medical Records 2007 Austin
  May 16, 2007
  Category 1, Hours: 3.0
  Ethics, Hours: 1.0

- The New York Eye & Ear Infirmary Institute
  for Continuing Medical Education–New Orleans, LA
  Managing Concomitant Eye Diseases: Expert Views
  on Glaucoma
  November 9, 2007
  Category 1, Hours: 1.50

- American Academy of Ophthalmology
  New Orleans, LA
  Subspecialty Day – Refractive Surgery
  November 9 & 10, 2007
  Category 1, Hours: 14.0

- American Academy of Ophthalmology
  New Orleans, LA
  Annual Meeting
  November 10 – 13, 2007
  Category 1, Hours: 9.0

- Texas Medical Association – Austin, TX
  Ocular Emergencies
  January 10, 2008

Category 1, Hours: 2.0

- University of Kentucky MedEDirect – Austin, TX
  NSAID Therapy from a Retinal Perspective
  February 21, 2008
  Category 1, Hours: 1.0

- IntraLase Technology – Austin, TX
  Physician Certification Program on
  IntraLase Technology
  March 3, 2008
  Certification

- University of Kentucky – Austin, TX
  Glaucoma Therapy and the Ocular Surface
  March 27, 2008
  Category 1, Hours: 1.0

- Texas Health Resources – Dallas, TX
  30th Annual Spring Ophthalmology Symposium
  April 18, 2008
  Category 1, Hours: 6.5

- University of Kentucky – Austin, TX
  Ocular Allergy Learnings
  April 17, 2008
  Category 1, Hours: 1.0

- UT Southwestern Alumni Reunion – Dallas, TX
  Science and Faith
  April 26, 2008
  Category 1, Hours: 1.0

- Texas Medical Association – Austin, TX
  Retina Case Conundrums 2008,
  Current Concepts in ROP
  May 8, 2008
  Category 1, Hours: 2.0

- Texas Medical Association – Austin, TX
  Promoting Physicians' Personal & Professional
  Fulfillment
  May 22, 2008
  Ethics, Hours: 1.0

- American Academy of Ophthalmology– Atlanta, GA

2008 Subspecialty Day – Refractive Surgery
November 7 & 8, 2008
Category 1, Hours: 14.0

- American Academy of Ophthalmology- Atlanta, GA
  2008 Joint Meeting
  November 8-11, 2008
  Category 1, Hours: 13.0

- Endo Optiks, Inc. – Austin, TX
  Endoscopic Cyclophotocoagulation using the
  E2 Compact Microprobe™ Laser Endoscopy System
  May 19, 2009
  Certification

- Chylack, Inc. – Austin, TX
  Lens Opacities Classification System Version III
  (LOCS III)
  August 1, 2009
  Certification

- National Retina Institute – San Antonio, TX
  Ophthalmic Symposium
  August 28-30, 2009
  Category 1, Hours: 11.0

- American Academy of Ophthalmology –
  San Francisco, CA
  2009 Joint Meeting
  October 24-27, 2009
  Category 1, Hours: 10.0

- The Dulaney Foundation – San Francisco, CA
  Prime Time CME Symposium
  October 25, 2009
  Category 1, Hours: 2.0

- The New York Eye And Ear Infirmary
  Institute for Continuing Medical Education
  San Francisco, CA
  Solving Diagnostic and Treatment Dilemmas with
  New Options for Ocular Infection and Inflammatory
  Conditions
  October 26, 2009
  Category 1, Hours: 1.5

- Lucentis RVO Program – Austin, Texas
  July 22, 2010
  Informal Hours: 1.0 hour

- Ophthalmic Symposium – San Antonio, Texas
  August 27-29, 2010
  Category 1, Hours: 11.0

- National Institutes of Health (NIH)
  Office of Extramural Research
  Protecting Human Research Participants
  September 7, 2010
  Certificate Number: 253583

- American Academy of Ophthalmology –
  Chicago, IL
  2010 AAO Annual Meeting
  January 15, 2011
  Category 1, Hours: 12.0

- American Academy of Ophthalmology –
  Chicago, IL
  Subspecialty Day: Refractive Surgery
  January 15, 2011
  Category 1, Hours: 12.0

- American Society of Cataract and Refractive Surgery –
  San Diego, CA
  Eyeworld CME Educational Symposia
  Ethics of the Premium Channel
  March 27, 2011
  Category 1, Hours: 1.0

- Ophthalmic Symposium – San Antonio, Texas
  August 27-28, 2011
  Category 1, Hours: 11.5

- University of California School of Medicine –
  San Francisco, California
  UCSF Glaucoma Update 2011
  September 23 – 24, 2011
  Category 1, Hours: 14.25

- Texas Medical Association – Austin, Texas
  Beyond the White Coat: Physicians and Their Loved Ones
  October 4, 2011
  Category 1, Hours 1.0

- Hawaiian Eye 2012 – Wailea, Maui
  Vindico Medical Education
  Taming Inflammation on the Ocular Surface: A Closer Look at Dry Eye.
  January 15, 2012
  Category 1, Hours 1.0

- Hawaiian Eye 2012 – Wailea, Maui
  Vindico Medical Education
  Practice Management: The Business of Ophthalmology
  January 15, 2012
  Category 1, Hours 1.5

- Hawaiian Eye 2012 – Wailea, Maui
  Vindico Medical Education
  Cataract/IOL
  January 16, 2012
  Category 1, Hours 4.0

- Hawaiian Eye 2012 – Wailea, Maui
  Vindico Medical Education
  Cataract Surgery Complications; Mini Symposium on Femtosecond-Assisted Phacoemulsification; and Panel Discussion: Refractive Surgery Complications.
  January 17, 2012
  Category 1, Hours 4.0

- Hawaiian Eye 2012 – Wailea, Maui
  Vindico Medical Education
  Glaucoma
  January 18, 2012
  Category 1, Hours 4.0

- Hawaiian Eye 2012 – Wailea, Maui
  Vindico Medical Education
  Current Perspectives on the Optimal Management of Postsurgical Ocular Inflammation
  January 18, 2012

Category 1, Hours 1.0

- Hawaiian Eye 2012 – Wailea, Maui
  Specialty Symposium: Medical Retina Update for the Comprehensive Ophthalmologist; Management of the Ocular Surface, Part 1; and Management of the Ocular Surface, Part 2.
  January 19, 2012
  Category 1, Hours 4.0

- Hawaiian Eye 2012 – Wailea, Maui
  Best Practices for Optimizing Postsurgical Outcomes
  January 19, 2012
  Category 1, Hours 1.0

- PPD – Sunovion Training – Austin, Texas
  Protocol review, highlights, Ophthalmic key points, Logistics and training.
  August 28, 2012
  Informal: 1 hour

- Texas Medical Association – Austin, Texas
  International Ophthalmology
  October 23, 2012
  Ethics, Hours 1.0

- American Academy of Ophthalmology – Chicago, IL
  2012 AAO Annual Meeting
  November 9 – 13, 2012
  Category 1, Hours: 20.0

- ACES/SEE Caribbean Eye Meeting – San Juan, PR
  February 8 – 12, 2013
  Category 1, Hours: 17.0

- Glaukos® – Austin, Tx
  April 15, 2013
  Glaukos® Physcian Training Program
  Glaukos iStent® Trabecular Micro-Bypass Stent
  Certificate of Completion

- Ophthalmic Symposium – San Antonio, Tx
  August 24-25, 2013
  Category 1 Hours: 11.5

Thomas Henderson, M.D., F.A.C.S.

09/19/16

Date

TEXAS MEDICAL BOARD

P.O. BOX 2029 • AUSTIN, TEXAS 78768-2029

PHYSICIAN FULL PERMIT

LICENSE/PERMIT NUMBER

F4863

EXPIRATION DATE

08/31/2019

THOMAS THOMAN HENDERSON, MD
3410 FAR WEST BLVD STE 140
AUSTIN TX 78731-3167

THIS CERTIFIES THAT THE LICENSEE/PERMIT HOLDER NAMED AND NUMBERED HEREON HAS PROVIDED THIS BOARD THE INFORMATION REQUIRED AND HAS PAID THE FEE FOR REGISTRATION FOR THE PERIOD INDICATED ABOVE
PLEASE KEEP THIS BOARD NOTIFIED OF CHANGE OF ADDRESS

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Thomas Henderson** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 09/10/2016.

Certification Number: 1786606.

VALERIE E. GATAVASKI, COA
9100 WATERFORD CENTRE BOULEVARD #271 AUSTIN TX. 78758
(860)861-4470, vewash@yahoo.com

PROFILE

Well organized and proficient at multitasking. Extremely detail oriented and focused. Highly effective verbal and written communication skills. Maintain professionalism while working with patients in an empathetic and caring manner. Easy to work with; a cooperative and supportive team player.

CAREER HIGHLIGHTS

EYE CLINIC OF AUSTIN, Austin TX — 2015 to Present
Certified Ophthalmic Assistant
Research/Study Coordinator

- Preliminary and ancillary testing includes the use of manual/automated lensometry.
- EHR/EDC documentation of all patient/subject histories, performed and recorded visual acuity.
- Proficient at pupil assessment, manual refraction with the use of phoropter, trial frame and lenses.
- Proficient in the use of Humphrey Visual Field Analyzer, Optical Coherence Tomography and Optos.
- Proficient in the assessment of intraocular pressure by means of Goldmann, Tonopen and Perkins devices.
- Proficient with EDC entries, maintaining all subject study binders, handling /shipping of specimens.
- Proficient in filing reports to a central or local IRB per study.
- Protocol, Informed Consent construction, current GCP, NIH, IATA certificates

MIDDLESEX EYE PHYSICIANS, Middletown, CT — 2012 to 2015
Certified Ophthalmic Assistant

- Preliminary testing, patient histories, assessment of visual acuity, manual refractions and assessment of intraocular pressure.
- Ascan, ultrasound biometry, acquired corneal curvature, axial length, anterior chamber depth using the IOL Master, Lenstar, Verion, manual Ascan with immersion, manual keratometry.
- Corneal assessment using Zeiss Corneal Topographer.

THE EYE CARE GROUP, New Haven CT — 2001 to 2012
Ophthalmic Assistant/Surgery Coordinator

- Met with patients, scheduled all appointments for surgical procedures, prepared necessary paperwork
- Scheduled and followed up on all ancillary testing prior to procedures.
- Acquired any necessary authorization/pre-certification from insurance carriers.

- Counseled patients with regard to proposed procedures, including the use of pre/post operative medication and restrictions. Informed the surgeons of schedules including revisions, routing all charts to the surgeons in a timely manner prior to the day of surgery
- Informed the surgeons of schedules including revisions, routing all charts to the surgeons in a timely manner prior to the day of surgery.

EDUCATION

National Institutes of Health - Good Clinical Practice and Protection of Human Research Subjects
JCAHPO Certification - Certified Ophthalmic Assistant
Stone Academy, Hamden CT – Medical Assisting
Wilbur L Cross High School, New Haven, CT – Diploma

ORGANIZATIONS

ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS
MEMBER 2016
SOCIETY OF CLINICAL RESEARCH ASSOCIATES
MEMBER 2017

updated 10-18-17 Valerie E Ostapowski, COA

JOINT COMMISSION ON ALLIED HEALTH PERSONNEL IN OPHTHALMOLOGY®

2025 Woodlane Drive • St. Paul, Minnesota 55125-2998
PHONE (651) 731-2944 • (800) 284-3937 • FAX (651) 731-0410

CERTIFICATION I.D.

NAME **Valerie E. Gatavaski**

I.D.# **209805**

CERTIFICATION LEVEL **COA®**

EXPIRATION DATE **December 31, 2019**

SOCRA
FOR CLINICAL RESEARCH EXCELLENCE

Clinical Research Education/Professional Certification

Valerie E. Gatavaski
Member ID 60486
Member through 8/1/2018

MEMBERSHIP CARD
www.socra.org

BASIC LIFE SUPPORT

BLS Provider

American Heart Association®

VALERIE E. GATAUASKI

The above individual has successfully completed the cognitive and skills evaluations in accordance with the curriculum of the American Heart Association Basic Life Support (CPR and AED) Program.

11-17-2016
Issue Date

11/2018
Recommended Renewal Date

BASIC LIFE SUPPORT

Training Center Name: A-TCEMS
TC ID #: TX04794

TC Info: Austin, TX 78721 ZIP TO 512-978-0100

Course Location: 3410 Far West Blvd. Ste 140

Instructor Name: Sherry P. Hamilton
Inst. ID #: 03130159373

Holder's Signature: Valerie E Gataiuski

 15-1805

EYE CLINIC
OF AUSTIN

PI/SITE NAME:_____

SUBJECT NAME:_____

DOCUMENTING THE CONSENT PROCESS

Date:_____

Consent Forms (CFs) reviewed:

☐ Main Study CF, Version/Date:_____

Language of CF(s) reviewed:

☐ English ☐ Spanish ☐Other, Specify:_____

Study Staff Member(s) Conducting CF discussion:_____

Was time allowed to ask/answer questions? ☐ Yes ☐ No

If not, please explain:_____

Was a copy of the signed CF(s) provided to the study subject? ☐ Yes ☐ No

If not, please explain:_____

Was/were the CF(s) signed prior to initiation of study procedures? ☐ Yes ☐ No

If not, please explain:_____

Additional Notes:

_____ _____

Signature of person obtaining consent Date

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27 DEC 2017

INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

A. REPORTING GUIDELINES:

If you are not familiar with Salus IRB reporting requirements regarding unanticipated problems (UPs), deviations, and other safety information, refer to the guidance document, "Reporting Guidelines For Unanticipated Problems, Deviations, and Other Safety Information," on the Salus IRB website.

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If you are required by your site or sponsor policy to submit IND Safety, MedWatch, SUSAR, or CIOMS Reports, or other safety information that does not meet the definition of an unanticipated problem and, therefore, does not require reporting to Salus IRB, use this form.

Salus IRB does not require reporting of minor protocol deviations. If you are required by your site or sponsor policy to submit minor protocol deviations, use this form.

For those events that Salus IRB does not require to be reported, if in the PI's judgment, any adverse events, minor protocol deviations or other events, when considered together indicate that changes to the research plan and/or consent form should be made, then the PI should provide an analysis of the events and any rationale for suggested changes at the time of continuing review, interim review, and/or site closure.

B. REPORT TYPE:

1. [X] Minor Unplanned Protocol Deviation – is defined as an accidental or unintentional deviation from the Salus IRB-approved protocol that did not involve a new or increased risk to one or more research participants, did not adversely affect the rights, safety, or welfare of one or more participants, and did not adversely affect the conduct of the study.

   Examples are: participant missed visit due to holidays, participant failed to return diary, participant failed to initial every page of the consent form, or other deviations that involve only logistical issues or only affect administrative aspects of the study.

   a. Describe deviation or attach a description to this report (list each deviation being submitted by date of deviation and participant ID #):

OR

SUBJECT 11921 R-NL DEVIATION DATE 11 JUL 2018 VISIT 3
SUBJECTS VISIT 3 - 7 WEEKS OUT OF WINDOW DUE TO SCHEDULING CONFLICTS & SUBJECT TRAVELLING OUT OF THE AREA.

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

SPONSOR: GUARDIAN HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27DEC2017

INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

2. ☐ Adverse Event, IND Safety, MedWatch, SUSAR or CIOMS Report, or other safety information being submitted to satisfy site or sponsor reporting requirements, which does not meet the criteria of an unanticipated problem.

   a. Report Identifier (list each report being submitted by report number, date of report, and participant ID #):
   b. Report Type: ☐ Initial ☐ Follow-up #

OR

3. ☐ Other (please describe):

C. INVESTIGATOR OR SPONSOR REPRESENTATIVE STATEMENT:

My signature below indicates that I have reviewed the information provided in this report and the attached documents. I understand that Salus IRB requires only reporting of events determined to be unanticipated problems involving new or increased risks to participants or others. Further, I understand that because of this policy, Salus IRB does not require reporting of events which do not meet the unanticipated problem criteria. I therefore acknowledge that I am submitting this report and attached documents to satisfy my site or sponsor requirements. I understand that Salus IRB will not provide IRB review of this submission and that Salus IRB will only acknowledge receipt of this submission. Further, if I am not the Principal Investigator, by signing this form, I certify that I am authorized to submit this information and sign this form on the Principal Investigator's behalf.

THOMAS T HENDERSON MD
Printed Name of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor)

Thomas T Henderson MD 27 Sep 2018
Signature of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor) Date

SALUS IRB USE ONLY

IRB STAFF ACKNOWLEDGEMENT OF RECEIPT:

The information in this report was not reviewed by the IRB. This report has been received and filed in the IRB study file.

Trina Anderson
Printed Name of IRB Administrative Staff

Trina Anderson 01 Oct 2018
Signature of IRB Administrative Staff Date

Salus IRB

NON-REPORTABLE EVENT FORM
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SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27DEC 2017

INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

A. REPORTING GUIDELINES:

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   a. Describe deviation or attach a description to this report (list each deviation being submitted by date of deviation and participant ID #):

OR

SUBJECT 44-LBR DEVIATION DATE 20JULY 2018 VISIT 3. SUBJECTS VISIT 3 2WEEKS OUT OF WINDOW DUE TO AN UNFORESEEN SCHEDULING CONFLICT ON BEHALF OF THE SUBJECT.

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27DEC2017

INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

2. ☐ Adverse Event, IND Safety, MedWatch, SUSAR or CIOMS Report, or other safety information being submitted to satisfy site or sponsor reporting requirements, which does not meet the criteria of an unanticipated problem.

   a. Report Identifier (list each report being submitted by report number, date of report, and participant ID #):
   b. Report Type: ☐ Initial ☐ Follow-up #

OR

3. ☐ Other (please describe):

C. INVESTIGATOR OR SPONSOR REPRESENTATIVE STATEMENT:

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THOMAS T HENDERSON MD
Printed Name of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor)

Thomas T Henderson MD 27 Sep 2018
Signature of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor) Date

SALUS IRB USE ONLY

IRB STAFF ACKNOWLEDGEMENT OF RECEIPT:

The information in this report was not reviewed by the IRB. This report has been received and filed in the IRB study file.

Irina Anderson
Printed Name of IRB Administrative Staff

Irina Anderson 01 Oct 2018
Signature of IRB Administrative Staff Date

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27DEC2017

INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

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   a. Describe deviation or attach a description to this report (list each deviation being submitted by date of deviation and participant ID #):

OR

SUBJECT 8476 OUV DEVIATION DATE ON JULY 2018 VISIT 3 SUBJECT'S PCP INTERRUPTED USE OF LUMEGA Z FOR 2 WEEKS TO R/O CAUSES OF SUBJECTS MINOR SPIKE IN BLOOD PRESSURE. LUMEGA Z FOUND NONCONTRIBUTORY TO ELEVATION OF BLOOD PRESSURE. ADDITIONAL HYPERTENSIVE MEDICATION PRESCRIBED. SUBJECT IS COMPLIANT RESUMED LUMEGA Z, A FOLLOW-UP TO THE PCP REVEALS A LOWERING OF SUBJECTS BLOOD PRESSURE.

Salus IRB

NON-REPORTABLE EVENT FORM
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SPONSOR:	**PROTOCOL #:**
INVESTIGATOR NAME:	

2. ☐ Adverse Event, IND Safety, MedWatch, SUSAR or CIOMS Report, or other safety information being submitted to satisfy site or sponsor reporting requirements, which does not meet the criteria of an unanticipated problem.

   a. Report Identifier (list each report being submitted by report number, date of report, and participant ID #):
   b. Report Type: ☐ Initial ☐ Follow-up #

OR

3. ☐ Other (please describe):

C. INVESTIGATOR OR SPONSOR REPRESENTATIVE STATEMENT:

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THOMAS T HENDERSON MD
Printed Name of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor)

Thomas T Henderson MD 27 Sep 2018
Signature of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor) Date

SALUS IRB USE ONLY

IRB STAFF ACKNOWLEDGEMENT OF RECEIPT:

The information in this report was not reviewed by the IRB. This report has been received and filed in the IRB study file.

Irina Anderson
Printed Name of IRB Administrative Staff

Irina Anderson 01 Oct 2018
Signature of IRB Administrative Staff Date

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27DEC2018

INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

A. REPORTING GUIDELINES:

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   a. Describe deviation or attach a description to this report (list each deviation being submitted by date of deviation and participant ID #):

OR

SUBJECT 18819 TJF. DEVIATION DATE 30 MAY 2018 VISIT 3.
SUBJECTS VISIT 3 3 WEEKS OUT OF WINDOW SECONDARY TO SCHEDULING CONFLICTS ON BEHALF OF THE SUBJECT & TRAVELLING OUT OF THE AREA.

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

SPONSOR: GUARDION HEALTH SCIENCES **PROTOCOL #:** 1 VERSION 2 27DEC2017
INVESTIGATOR NAME: THOMAS HENDERSON, M.D.

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OR

3. ☐ Other (please describe):

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THOMAS T HENDERSON MD
Printed Name of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor)

Thomas T Henderson MD 27 Sep 2018
Signature of Investigator/Authorized Designee (Site) or Sponsor Representative (Sponsor) Date

SALUS IRB USE ONLY

IRB STAFF ACKNOWLEDGEMENT OF RECEIPT:

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Irina Anderson
Printed Name of IRB Administrative Staff

Irina Anderson 01 Oct 2018
Signature of IRB Administrative Staff Date

Salus IRB

NON-REPORTABLE EVENT FORM
(SUBMISSION OF INFORMATION THAT SALUS IRB DOES NOT REQUIRE TO BE REPORTED)

2111 West Braker Lane, Suite 400 • Austin, TX 78758 • P: 512.380.1244 • F: 512.382.8902 • salus@salusirb.com

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OR

SUBJECT 4913 D-A DEVIATION DATE 2 MAY 2018 VISIT 2

① SUBJECT INTERRUPTED USE OF LUMEGA K/LUMEGA BOOST FOR 30 DAYS SECONDARY TO KNEE REPLACEMENT SURGERY. RESUMED USE ON JUNE 7, 2018

② ABOVE NAMED SUBJECT - DEVIATION DATE 18 MAY 2018 VISIT 2 SUBJECTS VISIT 2 11 DAYS OUTSIDE WINDOW SECONDARY TO KNEE SURGERY - INABILITY TO DRIVE & TRANSPORTATION ARRANGEMENTS MUST BE MADE TO KEEP APPOINTMENT.

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SPONSOR: Guardion Health Sciences **PROTOCOL #:** 1 Version 2 27 Dec 2017
INVESTIGATOR NAME: Thomas Henderson, MD.

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Thomas T Henderson MD 27 Sep 2018
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Printed Name of IRB Administrative Staff

Irina Anderson 01 Oct 2018
Signature of IRB Administrative Staff Date

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OR

SUBJECT 11039JAT DEVIATION DATE 22FEB2018 V.2
SUBJECT REPORTS- DECREASING LOVENOX 1 TO 1/2 DOSE DAILY SECONDARY TO GASTRO INTESTINAL ISSUES STARTING 30JAN2018.
SUBJECT DIAGNOSED WITH INTESTINAL PARASITES - CONTRACTED UPON EATING SEAFOOD WHILE ON VACATION - SUBJECT SEEN IN FOLLOW UP BY PCP, INTESTINAL ISSUES ARE RESOLVING.

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OR

Subject 11039 JAT Deviation Date 25 Apr 2018 Visit 2
Subject reports - Interrupted use of Lumena 2 of 7 days.
Secondary to the use of antibiotics for continued -
Gastrointestinal parasites. Subject has been seen in
Follow up by PCP - Issues appears resolved 30 Apr 2018.

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Irena Anderson
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OR

SUBJECT 4652-JBW DEVIATION DATE 17 MAY 2018 VISIT 2
(1) SUBJECTS VISIT 2 6 WEEKS OUT OF WINDOW SECONDARY TO HEALTH ISSUES.
(2) ABOVE NAMED SUBJECT - DEVIATION DATE 22 APR 2018
- SUBJECT HAS MISSED UNKNOWN NUMBER OF DOSES OF LUMEGAN.
- SUBJECT ADMITS TO SHARING DOSES WITH SPOUSE.

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OR SUBJECT 1831 MTB DEVIATION DATE 4MAY2018 VISIT 2
(1) SUBJECT NOT DILATED AT VISIT PER THE PI BECAUSE OF (2) BELL'S PALSY. SUBJECT TO BE DILATED AT VISIT 3 IF PALSY IS RESOLVED -
(2). ABOVE NAMED SUBJECT MISSED DOSES DEV. DATE - 2 AUG 2018 VISIT 3 - SUBJECT MISSED DOSES THEN D/C LUMEGRA-T SECONDARY TO INTESTINAL UPSET & LETHARGY. SUBJECT SEEN BY PCP DIAGNOSED WITH HSV - FLARE UP - AS OF 28 AUG 2018 HSV RESOLVED -

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Irina Anderson
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Irina Anderson
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01 Oct 2018
Date

Statistical Analysis Plan

At the end of the trail period, data will be collected by the Principal Investigator and analyzed by professional optical engineers at Western University of Health Sciences, Pomona CA. The data provided will only contain patient ID, age, and sex, without containing any identifying details about each participant. Data will be analyzed upon measurement quality, according to the respective manufacturer procedures, in each outcome measure. In the event which data is missing or incomplete, we will evaluate the appropriate measures to include the available information and consult with qualified professionals.

Preliminary and sub-analyses will be performed using the statistical programing software, SPSS Systems. The objective is to examine the distribution and potential relationships within data sets through standardized descriptive-numerical summaries. Statistical analysis strategies may include a mixed-design Analysis Of Variance (ANOVA) to examine the following outcome measures across the three time-points of data collection; including visual acuity, contrast sensitivity, dark adaptation recovery, and MPOD levels. A post hoc sub-analysis of paired sample t-test may be used (either Bonferroni correction or Tukey test) to evaluate the change in each outcome measure parameter, if needed, in respect to each treatment group. Additionally, each group-measurement may be separated and analyzed by eye; to evaluate inter-eye differences from each treatment. Results of the statistical analysis will be analyzed as group averages of each outcome measurement.