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RESEARCH INTEGRITY AND COMPLIANCE
THE UNIVERSITY OF UTAH

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IRB_00065178 **Created:** 5/5/2013 4:38 PM

PI: Bradley Katz M.D., Ph.D. **Submitted:** 7/17/2013

Title: Thin film spectacle coatings to reduce light sensitivity and headaches in child and adolescent patients with migraine

1. Study Introduction

1. **Responsible Investigator:**
Bradley Katz

Email	Training	CoI Date
bradley.katz@hsc.utah.edu	4/11/2019 MCG	1/16/2020

a. **Position of the Investigator:**

- (●) **Faculty or** Non-Academic Equivalent
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

2. **Contact Persons for the Responsible Investigator:**

Name	Email	Training
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/10/2017 MC
Elizabeth Nuttall	Elizabeth.Nuttall@hsc.utah.edu	3/3/2017 MCG
Katie Rogers	katie.rogers@utah.edu	7/20/2017 MC

3. **Guests of the Responsible Investigator:**

Last Name	First Name	E-Mail
There are no items to display		

4. **What type of application is being submitted?**
New Study Application (or Amendment/Continuing Review)

5. **Title Of Study:**
Thin film spectacle coatings to reduce light sensitivity and headaches in child and adolescent patients with migraine

6. **Study Purposes and Objectives:**

Objectives: The long-term goal of the project is to reduce the severity and frequency of migraines in child and adolescent patients who are sensitive to light. The goal of this protocol is to test an optical filter that blocks the wavelengths of light known to trigger migraines.

A co-PI is developing thin film coatings that will be applied to spectacle lenses. In this protocol, the investigators will determine the efficacy these prototype filters in a cohort of migraine patients.

7. **Is this a multi-site study, where more than one site needs IRB approval?**
   ○ Yes ● **No**

8. **Background and Introduction:**

Background and Introduction: Nearly all migraine sufferers report sensitivity to light during a headache and a significant proportion of sufferers report light sensitivity between attacks. Light is also a common trigger for migraine headaches. Preliminary evidence indicates that migraine patients may be more sensitive to a particular portion of the visible spectrum. We hypothesize that if we could selectively block this portion of the visible spectrum, we could reduce the frequency and severity of headaches in migraine patients. The objective of this proposal is to develop coatings that can be applied to spectacle lenses, contact lenses, and light sources that will block the target wavelengths. The filters will then be tested in a cohort of adult patients with migraines. If successful, these filters could be a novel, non-invasive adjuvant in the treatment of migraines.

Approximately 9% of men and 18% of women are afflicted with migraines. (Stovner, 2006) Over 90% of patients with migraines report a sensitivity to light (photophobia) during headaches. (Evans, 2008) Some migraine sufferers report that light can trigger a migraine and some have a chronic sensitivity to light. (Main, 1997) Migraineurs are especially sensitive to non-incandescent lighting sources such as fluorescent lights, computer monitors, and gas-vapor lamps.

A study took place in 1991 to determine if tinted spectacle lenses designed to block a specific wavelengths of light could reduce the frequency and severity of migraines. The tint, named “FL-41”, filtered light in the blue spectrum around the 480nm wavelength. The researchers found that the tinted spectacle lenses *reduced the frequency of migraines from 6.2 per month to 1.6 per month* in a cohort of children with migraines. (Good 1992) Since that time, we have prescribed the FL-41 tint to a number of Moran Eye Center patients. Anecdotally, more than 80% of our patients report that the tint improves symptoms of photophobia and headache. For some patients, the improvement can be dramatic, allowing patients disabled by headache and photophobia to return to work. As an example, one Moran Eye Center patient recently wrote that the fluorescent lights at church and at the City Hall where she volunteers triggered horrible migraines. After being prescribed spectacles with the FL-41 tint, she now leaves those locations “feeling fantastic” and looks forward to “enjoying my family instead of nursing a migraine and taking a nap.” Furthermore, we’ve recently demonstrated the effectiveness of FL-41 in another light sensitive condition, benign essential blepharospasm. (Blackburn, 2009)

Although FL-41 has been shown to be an effective treatment, **this tint has drawbacks that limit its efficacy and acceptance by patients**. For example:

- FL-41 has a rose-colored appearance that some patients find objectionable
- FL-41 distorts vision to a rose-colored perception
- FL-41 can only be applied to plastic spectacle lenses and cannot be applied to glass lenses, contact lenses or light sources
- Quality control in the manufacture of FL-41 is poor and we have previously demonstrated that there is considerable variation in the transmission characteristics of FL-41 purchased at various optical shops. (Katz, 2002)
- Because FL-41 filters neighboring wavelengths in addition to the target wavelength, there’s a limit to how much you can block without making the tint too dark for indoor use.
- **This research team will develop a light filtering technology to overcome the drawbacks of the FL-41 tint.** This filter coating is colorless, does not distort color perception, and can be used indoors or outdoors. The filter coating can be applied to not only plastic spectacle lenses, but also glass lenses, contact lenses, and even light bulbs and computer monitors. Furthermore, because the filter will block only the specific, target wavelengths it will likely be more effective than FL-41.

The filter coating will be different than FL-41 because it is not a *color filter.* Color filters are glasses or plastics that are doped with materials that naturally absorb portions of the light spectrum and have the drawbacks listed above. In contrast, the filter coating developed by this research team will use “thin-film” technology. Multi-layer “thin film” technology consists of alternating layers of transparent materials. The anti-reflection coating commonly found in optical shops is in fact a thin film applied to spectacles. Multiple layers of thin films can be designed to block narrow regions of the light spectrum.

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2. Study Location and Sponsors

1. **Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).**

   Click the appropriate button(s) below to add locations:

	Site Name	Investigators Name	Covered Entity	Sub Sites
View	Intermountain Primary Children's Hospital		Yes	
View	University of Utah		Yes	

2. **Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study for the sites listed in this application?**
   ○ Yes ● **No**

3. **Indicate the source(s) of funding obtained or applied for to support this study.**

Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type
There are no items to display				

4. **Does this study have functions assigned to a Contract Research Organization (CRO)?**
   ○ Yes ● **No**

5. **Does this study involve use of the Utah Resource for Genetic and Epidemiologic Research (RGE)?**
   Examples: Utah Population Database (UPDB), Utah Cancer Registry (UCR), All Payers Claims Database (APCD), etc.
   ○ Yes ● **No**

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Addition of a Site

1. **Site Name:**
   Intermountain Primary Children's Hospital
2. **Site Principal Investigator**
   ☐ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   a. **Position of the Site Principal Investigator**
   b. **Will the Site PI consent participants?** ○ Yes ○ No
3. **Site Contact Persons, if different from the Site PI:**
   ☐ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training

There are no items to display

4. **Site Staff and Sub-Investigators**

Name	Email	Training	Obtaining Consent	CoI Date
Katie Rogers	katie.rogers@utah.edu	7/20/2017 MC	☑	12/22/2017

5. **Site Guests:**

Name	Email	Training

There are no items to display

6. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
7. **Select the study procedures that will be conducted at this site:**
   There are no items to display
8. **Select the University of Utah department responsible for this research:**
9. **Add any additional sites that are part of this performance group**
   There are no items to display

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Addition of a Site

1. **Site Name:**
   University of Utah
2. **Site Principal Investigator**
   ☐ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   a. **Position of the Site Principal Investigator**
   b. **Will the Site PI consent participants?** ○ Yes ○ No
3. **Site Contact Persons, if different from the Site PI:**
   ☐ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training
There are no items to display		

4. **Site Staff and Sub-Investigators**

Name	Email	Training	Obtaining Consent	CoI Date
Katie Rogers	katie.rogers@utah.edu	7/20/2017 MC	☑	12/22/2017

5. **Site Guests:**

Name	Email	Training
There are no items to display		

6. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)
7. **Select the study procedures that will be conducted at this site:**
   There are no items to display
8. **Select the University of Utah department responsible for this research:**
   PEDIATRIC NEUROLOGY
9. **Add any additional sites that are part of this performance group**
   There are no items to display

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3. Participants

1. Ages of Participants:

7 to 17 years old (Parental permission and assent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):
8-18 years

3. Indicate any vulnerable participant groups (other than children) included:

None

If "Other", please specify:

If "None" and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
○ Yes ○ No

4. Number of participants to be included and/or enrolled in this entire study, across all study locations: 50

At Utah prior to October 2019: 50

5. Characteristics of Participants/Inclusion Criteria:

1. Must be diagnosed with migraine with aura or migraine without aura
2. Must have at least 10 headache days per month

6. Participant Exclusion Criteria:

1. Currently wearing a spectacle tint specifically prescribed for migraine or light sensitivity
2. Pregnant
3. Unwilling or unable in the judgment of the investigator to complete the study
4. Unavailable for any of the study visits
5. Light sensitive conditions: meningitis, iritis, blepharospasm, albinism
6. Degenerative diseases of the retina or optic nerve: diabetic retinopathy, ischemic optic neuropathy
7. Medications known to affect retinal or optic nerve function: hydroxychloroquine, chloroquine, ethambutol, amiodarone, erectile dysfunction drugs
8. Best corrected visual acuity less than 20/40 in either eye

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?

○ Yes ● **No**

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Vulnerable Populations

Justification Requirements for the Inclusion of Vulnerable Populations

1. **How does the nature of the research require or justify using the proposed subject population?**
   Very few migraine medications are specifically approved for use in the pediatric population. Specially coated spectacles could represent an effective, non-pharmacologic adjuvant in the treatment of migraine and light sensitivity in this population.
2. **Would it be possible to conduct the study with other, less vulnerable subjects?**
   ○ Yes ● **No**

   If yes, justify the inclusion of vulnerable subjects:
3. **Is this population being included primarily for the convenience of the researcher?**
   ○ Yes ● **No**

   If yes, explain:
4. **Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?**

   ● **Yes** ○ No

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4. Study Information

1. **Design of Study (select all that apply):**
   Survey/Questionnaire Research
   Prospective Clinical Research

   If Other, describe:

2. **Does your study involve the use of any placebo?**
   ○ Yes ● **No**

3. **Length of entire study, from initiation through closeout:**
   2 years

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**

   In-person contact (e.g., patients, students, etc.)

   Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   Subjects will be recruited directly from the clinics of the investigators. Flyers will be posted in the clinics. When potentially qualifying patients are identified, the clinic staff will contact the study coordinator to consent the patient that day, or if the patient/parent have given permission for the study team to contact them by phone, the clinic staff will provide patient/parent contact information to the study coordinator so she may follow up with the family about the study.

   The study will be described to the patient and their family. Patients who express an interest will be invited to participate.

   Patients/families may consent the same day they are informed about the study, or at a later time. They are welcome to arrange a separate appointment to consent and enroll in the study if they wish.

   No database pools or participant pools will be utilized.

5. **How will consent be obtained?**

   Informed Consent Process (with or without a document)

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

   Once a subject meets eligibility criteria, informed assent will be obtained from the subject and informed consent will be obtained from the parent or guardian. With the help of their parent/guardian, subject will complete a brief questionnaire and the HIT-6 ("Headache Impact Test")

   Subjects will be asked to try on two different test lenses - each has a mirror coating that reflects light. One blocks light at 480 nm (a bluish color) and one that blocks light at 620 nm (an orange color). Subjects will be asked which lens they think would help most with their headaches.

Subjects will be asked to complete a headache diary every day for one month. During this month, no study lenses are worn. At the end of the first month, subjects return for visit 2/4. They fill out another questionnaire, another HIT-6 and receive study glasses. Subjects who already wear glasses will receive study glasses customized to their prescription. Subjects who do not wear glasses will receive plain spectacles (no prescription) with the study coating. Subject will be asked to wear the study glasses during all waking hours. They will continue to fill out daily diary entries.

At the end of the second month, subjects return for visit 3/4. Study glasses are returned, the third set of questionnaires are completed. If the subject did not find the initial glasses to be effective, they will be asked if they'd like to try the other coating. If yes, they undergo a 4-week washout period and are given a second set of study lenses. If no, they continue in the study for four more weeks, as outlined below and exit the study.

For the third and final month, subjects are not wearing any study glasses. Diaries continue to be kept. At the end of the third month, subjects return for visit 4/4. Diaries are returned and a final set of questionnaires are completed.

Only non-conflicted members of the research team or third parties will collect and analyze all data for this research. All data will be masked during the collection and analysis phases of the research.

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ● **Yes** ○ No

   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ● **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   Primary endpoint is a 30% reduction in HIT-6 scores. Secondary endpoints are a 30% reduction in headache frequency and severity. Questionnaires, HIT-6, and diary data will be used to evaluate these endpoints. The first and third months of the study serve as baseline data for subjects. Data collected during these two months will be compared to data collected during the second month, when study lenses are worn. A Student's T-test should be sufficient for evaluating these data.

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Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Study Location and Sponsors Page):**

   Katie Rogers — Intermountain Primary Children's Hospital; University of Utah

   List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).

2. **Describe the location(s) where consent will be obtained.**
   Primary Children's Medical Center in SLC and in Riverton

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**
   Because subjects will not undergo any intervention for one month, there will be no waiting period between the consent process and obtaining consent.

   Informed consent for all potential research participants will be obtained by a member of the research team who does not have any conflicts of interest related to this research or by an appropriate third party approved by the Individual Conflict of Interest Committee.

   Update for Continuing Review 2016: Authorization to obtain consent is now limited to Dr. Candee and Katie Farnsworth.

   Update for Amendment Changing PI to Dr. Katz: Authorization to obtain consent is now limited to Katie Farnsworth.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
   Study personnel obtaining consent will emphasize to potential participants that participation is strictly voluntary and that their decision to participate, or not participate, will not affect their care.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
   Study personnel will ask potential families if they'd like more time to make a decision about participation. Study personnel will ask potential families if they'd like to discuss the research with other family members or friends before making a decision to participate.

6. **Will a legally authorized representative (LAR) be used?**
   ○ Yes ● **No**

7. **Will a language other than English be used to obtain consent?**
   ○ Yes ● **No**

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**
   ○ Yes ● **No**

   If yes, complete the following:

   a. **Explain why the waiver of consent documentation is being requested.**

b. **Justification for the waiver is one of the following:**
There are no items to display

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5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:

   - The research intervention is conducted in a private place
   - Discussing the study with participants individually instead of in front of a group
   - The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected
   - Allowing for anonymous submission of surveys and questionnaires

   Other or additional details (specify):

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:

   - Storing research data on password protected computers or in locked cabinets or offices
   - Participant identifiers will be stored separately from the coded, participant data
   - All data that will be transferred or transported outside of the institution will be encrypted

   Other or additional details (specify):

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

   ○ Yes ● **No**

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:

   - Periodic review and confirmation of participant eligibility
   - Periodic review of informed consent documentation
   - Periodic review of the transfer/transcription of data from the original source to the research record

   Other additional details (specify):

5. **Who will be the primary monitor of the study data and documentation?**

   Select all that apply:

   - Principal Investigator

Study Coordinator or Research Nurse

Other or additional details (specify):

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
quarterly

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6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

Subjects who wear glasses may feel self-conscious about wearing glasses with a coating that looks "different" from standard spectacles. Subjects who do not wear glasses may feel self-conscious about wearing glasses.

2. Describe the potential benefits to society AND to participants (do not include compensation):

If effective, the experimental coating could become the first FDA-approved non-pharmcologic intervention for migraine. Very few prescription medications are approved by the FDA for use in children and adolescents. The experimental coating could eventually benefit migraine patients both inside and outside the study. These coatings are not regarded as a "cure"; They could be a useful adjuvant in migraine treatment.

3. Are there any costs to the participants from participation in research?

○ Yes ● **No**

If yes, specify:

4. Is there any compensation to the participants?

● **Yes** ○ No

a. If yes, answer the following:
Specify overall amount:
Up to a maximum of $80

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):
There will be "prizes" at 3 time points after filling out the required surveys at those time points (end of 1 month, 2 month and 3 months).

At the conclusion of the study participants will be given the option of keeping the study glasses or returning them to us and us paying them $20.

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):
Each time participants complete the required surveys (end of month 1, 2, and 3) they will be able to choose form one of the "prizes" below in the form of a gift card worth up to $20.

Prizes:

7 Peaks Water Park
Amazon
Barnes and Noble
Baskin Robbins
Boondocks Fun Center
Clark Planitarium
Cold Stone Creamery
Dinosaur Park
Domino's Pizza
Google Play gift card
Heber Valley Railroad
Hogle Zoo
iTunes gift card
Living Planet Aquarium

Momentum Indoor Climbing Gym
Pappa John's Pizza
Spotify premium gift card
Thanksgiving Point: Museum of Ancient Life
Thanksgiving Point: Nat Geo Mammoth Screen Theater
The Leonardo Mueseum
Tracy Aviary
wAIRhouse trampoline park

d. If applicable, explain plan for prorating payments if participant does not complete the study:
Participants will receive a gift card each time they complete a required survey. They may choose a gift card worth up to a maximum of $20 or a $20 check at the end of the study.

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7. HIPAA and the Covered Entity

1. **Does this study involve Protected Health Information (PHI) or de-identified health information?**
   ● **Yes** ○ No

   a. **Select the method(s) of authorization that will be used:**

   (Consent and) Authorization Document

   b. **Will PHI be disclosed outside the Covered Entity?**
   ● **Yes** ○ No

   To whom?
   FDA

   And for what purposes?
   Because the spectacle lenses may be considered an investigational medical device, the FDA may require access to PHI.

Does this study involve any of the following:

2. **The investigational use of a drug?**
   ○ Yes ● **No**
3. **The investigational use of a medical device?**
   ● **Yes** ○ No
4. **Is this an investigator-initiated drug or device trial lead by the Principal Investigator?**
   ● **Yes** ○ No
5. **Exposure to radioisotopes or ionizing radiation?**
   ○ Yes ● **No**
6. **A Humanitarian Device Exemption (HDE)?**
   ○ Yes ● **No**
7. **Genetic testing and/or analysis of genetic data?**
   ○ Yes ● **No**
8. **Creating or sending data and/or samples to a repository to be saved for future research uses?**
   ○ Yes ● **No**
9. **Are you introducing recombinant or synthetic nucleic acids (such as viral vectors, plasmids, or oligonucleotides, or cells containing recombinant or synthetic nucleic acids) or human pathogens (viruses, bacteria, etc.) into human research participants or collecting**

samples (blood, tissue, cells, etc) from human participants for research purposes?

○ Yes ● **No**

10. **Does this study involve any of the following?**

- **Cancer Patients**
- **Cancer Hypothesis**
- **Cancer risk reduction**
- **Cancer prevention**

○ Yes ● **No**

11. **Any component of the Center for Clinical and Translational Science (CCTS)?**

○ Yes ● **No**

The Clinical Services Core (CSC)?

○ Yes ● **No**

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Investigational Use of a Device

1. **What is the initial risk determination of the device study according to the investigator and/or sponsor?**

   The study is a non-significant risk (NSR) device study.

   a. **Provide IDE (or HDE) Number(s) for significant risk devices:**

IDE #	Device Name	IDE Holder

   There are no items to display

   b. **Attach verification of the IDE number for significant risk devices to the Documents and attachments page. Please check the method by which you choose to verify the IDE number:**
   There are no items to display

2. **Describe the plan to control, store, and dispense the investigational device. This plan should ensure that the device is only used by qualified investigator(s) for the participants enrolled in this research project.**
   Thin film coatings for spectacles are similar in design to anti-reflective coatings commonly dispensed for prescription and cosmetic eyewear. These coatings may be purchased without a prescription from a physician. They pose no risk to subjects. However, because they could be considered a medical "device", all study lenses will be numbered and stored in a locked cabinet. Only the PI, co-investigators, and study staff
   under the PI's direct supervision will have access to lenses and the PI will use an Excel log to track the location of all lenses.

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Non-Significant Risk Device

Review the following definition of a non-significant risk (NSR) device:

1. The medical device is not a significant risk device, because all of the following are true:
    a. The medical device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject.
    b. The medical device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.
    c. The medical device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.
    d. The medical device is does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.
2. The medical device is not banned.

1. **Provide justification of why the investigational medical device used in this study meets the definition of a NSR device.**
Thin film coatings for spectacles are similar in design to anti-reflective coatings commonly dispensed for prescription and cosmetic eyewear. These coatings may be purchased without a prescription from a physician. As such, the coatings do not present a potential for serious risk to the health, safety, or welfare of a subject.

The coatings are NOT intended as an implant, NOT purported or represented to be for use in supporting or sustaining human life, and NOT for use in the diagnosis or cure of disease. Although they are intended for the mitigation of migraine and photophobia, they do not present a serious risk to the health safety, or welfare of subjects.

These coatings are not banned.

Eyewear is not currently regulated by the FDA. Daily wear contact lenses and contact lens cleaning solutions are specifically cited as examples of NSR devices (http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf). By extension, it seems reasonable that the frames, lenses and coatings to be used in this study would also be considered NSR.

IRB_00065178 **Created:** 5/5/2013 4:38 PM

PI: Bradley Katz M.D., Ph.D. **Submitted:** 7/17/2013

Title: Thin film spectacle coatings to reduce light sensitivity and headaches in child and adolescent patients with migraine

8. Resources and Responsibilities

1. **State and justify the qualifications of the study staff:**

   All sub-investigators, study coordinators and research assistants to whom study-related tasks are delegated are qualified by education, training, and experience to perform the tasks the PI delegates to them. A qualified physician, or a nurse practitioner specialist in neurology, (i.e., the PI or an MD or FNP sub-investigator) is responsible for all medical-related decisions and care.

2. **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   Staff and investigators will hold regular meetings with the PI to discuss progress of the study, training to perform specific study procedures delegated by the PI, and training on regulatory requirements and proper conduct of a research study. The PI will maintain documentation of all
   CITI and other study-related training received by study staff.

3. **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**
   This study will be conducted at PCMC in the clinics of the investigators. Data analyses will take place in the offices of the investigators at PCMC, the Moran Eye Center and UUHSC.

4. **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
   Not applicable, minimal risk study.

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Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document(Highlighted Changes)

Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Parental Permission Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Assent Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

VA Consent Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Literature Cited/References:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
CV 2017 April.pdf	0.04	1/15/2016 6:10 PM	7/24/2017 7:15 AM	

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

Other Documents:

Name	Version	Date Created	Date Modified	Date Approved
There are no items to display				

IRB_00065178 **Created:** 5/5/2013 4:38 PM

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Title: Thin film spectacle coatings to reduce light sensitivity and headaches in child and adolescent patients with migraine

Finish Instructions

Finish Instructions

1. **To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**

IRB_00065178 **Created:** 5/5/2013 4:38 PM

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Title: Thin film spectacle coatings to reduce light sensitivity and headaches in child and adolescent patients with migraine

Intermountain Primary Children's Hospital
The Child First and Always®

PCH Administrative Research Questions

You have indicated Primary Children's Hospital is a study location. Please complete the following questions so Primary Children's can confirm that your study:

1. Aligns with Primary Children's Mission, Vision and Values
2. Receives approval from the Primary Children's resources impacted (e.g.: lab, radiology, infant unit, etc.); and
3. Identifies Primary Children's study related charges from standard of care charges

If you have any questions or concerns regarding this form or the associated Primary Children's approval process, please contact:

Brenda Maldonado
Research IRB Coordinator
Pediatric Education Services
Intermountain Primary Children's Hospital

Email: brenda.maldonado@imail.org
Phone: 801-507-9248

Principal Investigator: Bradley Katz , 5-6653, bradley.katz@hsc.utah.edu
Contact Person(s):

Last Name	First Name	E-Mail	Phone
Harrison	Deborah	deborah.harrison@hsc.utah.edu	5-6645
Nuttall	Elizabeth	Elizabeth.Nuttall@hsc.utah.edu	801-213-3461
Rogers	Katie	katie.rogers@utah.edu	801-585-6647

IRB_00065178
Title: Thin film spectacle coatings to reduce light sensitivity and headaches in child and adolescent patients with migraine
Description of Study:

Objectives: The long-term goal of the project is to reduce the severity and frequency of migraines in child and adolescent patients who are sensitive to

light. The goal of this protocol is to test an optical filter that blocks the wavelengths of light known to trigger migraines.

A co-PI is developing thin film coatings that will be applied to spectacle lenses. In this protocol, the investigators will determine the efficacy these prototype filters in a cohort of migraine patients.

Assigned IRB Coordinator: Hannah Owen
Anticipated Length of Study: 2 years

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1. **Describe how this study furthers excellence in the provision of health care for children.**
   Very few treatments are approved for the treatment of migraine in kids. The spectacle coating we've developed may become the first non-pharmacologic FDA-approved treatment for pediatric migraine.

2. **In simple, brief and specific terms, tell us what this study will be doing.**
   We will recruit kids with migraine who are suffering more than 10 headache days per month. For the 1st and 3rd month of the study, subjects will not wear any special glasses, but will carefully track the frequency and severity of their headaches. During the 2nd month, subjects will be asked to wear spectacles with a coating that has been developed to reduce light sensitivity, migraine frequency and migraine severity. Subjects who don't already wear glasses will be given non-prescription spectacles. Subjects who already where glasses will get custom-coated lenses with their prescription. The coating is safe for wear indoors and out. We hope to observe a statistically significant reduction in migraine frequency and severity in our subjects.

3. **Project Funding Type:**

Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type

There are no items to display

Where is the funding for the project coming from?

4. **Will data be pulled from any PCH or Intermountain electronic system(s)?**
   ○ Yes ● **No**

5. **Do you need a qualified data analyst from intermountain to query an Intermountain or PCH database in order to produce a limited data set for your study?**
   ○ Yes ● **No**

6. **Will individuals associated with this study need to be granted access to PCH or Intermountain information systems?**
   ○ Yes ● **No**

7. **Will patient consent be obtained for access to the patient information?**
   ● **Yes** ○ No

8. **Could there be any inventions developed from this research?**
   ● **Yes** ○ No

   a. **If Yes, can you identify a date of the first written description or test of each invention?**
      a patent application for the experimental coating has been submitted to the USPO and EUPO.

b. **If Yes, has there been any communication about any of these inventions to others?**
● **Yes** ○ No
If yes, identify to whom and on what date.
see above; preliminary patent application is in the public domain and can be accessed through Google Patents

9. **Does this study involve inpatients?**
○ Yes ● **No**

10. **Does this study involve outpatients?**
● **Yes** ○ No

a. **Percent Inpatient:**

b. **Percent Outpatient:**
100

c. **Check all that apply:**
Other (List)
If Other, please list:
neurology

11. **Will ANY of the participants be non-English speaking?**
○ Yes ○ No

12. **Does this study involve any other PCH departments?**
○ Yes ● **No**

13. **Will the PI, study coordinator, research assistant or other person associated with this proposal need access to PCH facilities, systems, or equipment that they don't already have?**
○ Yes ● **No**

14. **Will PCH staff be required to perform any duties associated with this study in addition to routine patient care activities?**
○ Yes ● **No**

15. **Are diagnostic studies required as part of this study?**
○ Yes ● **No**

16. **Are any diagnostic studies requested above standard of care intended to be charged to an institutional account?**
○ Yes ● **No**

17. **This study is not an investigational drug study.**
This study is an investigational use of a medical device study.

Participants PCH 1st year:
30
Participants PCH total study:
50

18. ## Cybersecurity Questions for Intermountain

Intermountain CyberSecurity conducts risk assessments on research projects involving Intermountain Data. Intermountain Data is considered to be any information that originates from an Intermountain owned and/or managed information system. For example: iCentra, HELP2, Intermountain's EDW, SelectHealth, etc. The following set of questions is designed to gather study-specific information regarding data handling and security considerations for any component of the research project using Intermountain Data or systems and should be answered within this context.

Chart Review

For the purposes of this study will you export, transcribe, abstract, or otherwise copy information from an Intermountain information system?

○ Yes ○ No

Please contact us with any questions or concerns regarding completion of this. Please note both IRB approval and PCH administrative approval is required prior to starting the project. Thanks again for your support as together we put the *Child First and Always.*
brenda.maldonado@imail.org || 801-507-9248