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IRB_00086498 **Created:** 9/19/2015 4:57 PM

PI: Bradley Katz M.D., Ph.D. **Submitted:** 3/29/2016

Title: Spectacle Tints and Thin-Films to Reduce Headache Frequency in 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
Susan Bracken	sbracken@hsc.utah.edu	3/31/2018 MCG
YAIRA GARZON	YAIRA.GARZON@ECRESEARCH.ORG	G
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/10/2017 MC
Elizabeth Nuttall	Elizabeth.Nuttall@hsc.utah.edu	3/3/2017 MCG
Samuel Taylor	u6011742@utah.edu	1/28/2020 MG

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

Last Name	First Name	E-Mail
GARZON	YAIRA	YAIRA.GARZON@ECRESEARCH.ORG

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

5. **Title Of Study:**
Spectacle Tints and Thin-Films to Reduce Headache Frequency in Patients with Migraine

6. **Study Purposes and Objectives:**

Previous research has shown that both spectacle tints and spectacle thin-films can be an effective treatment in migraine. The purpose of this study is to determine if one of these treatments, tints or thin-films, is superior to the other.

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

8. **Background and Introduction:**

Brief Description

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. Spectacle lenses that have been treated with tints and spectacle lenses that have been treated with thin-films have both been shown to reduce light sensitivity and headache in patients with migraine. At this time, it is not clear which spectacle lens treatment is superior. The purpose of this trial is to determine if there's a significant, therapeutic advantage to either spectacle lens treatment. Both treatments could be a novel, non-invasive adjuvant in the treatment of migraine.

Detailed description

Approximately 6% of men and 18% of women are afflicted with migraines. (Stovner et al., 2006) Over 90% of patients with migraines report a sensitivity to light (photophobia) during headaches. (Evans et al., 2008) Some migraine sufferers report that light can trigger a migraine and some have a chronic sensitivity to light (Main et al., 1997). Migraineurs are especially sensitive to non-incandescent lighting sources such as fluorescent lights, computer monitors, and gas-vapor lamps (Katz and Digre, 2016).

The pathway that mediates photophobia appears to involve intrinsically photosensitive retinal ganglion cells ("IPRGCs"; Hattar et al., 2002) and trigeminal afferents (Noseda et al., 2010; Digre and Brennan, 2012). These retinal cells do not require input from photoreceptors to be activated by light, and they have been shown to be responsible for circadian rhythm entrainment and the pupillary light reflex. As such, these cells constitute a pathway separate from that of the visual pathway (Güler et al., 2008). IPRGCs contain the chromophore melanopsin. In these cells, 480 nm light (in the blue-green portion of the visible spectrum) isomerizes melanopsin and triggers the phototransduction cascade. However, IPRGCs can also be stimulated by rods and cones. Thus, IPRGCs can be stimulated *directly* by 480-nm light or *indirectly* by any light in the visible spectrum.

In the present study, we will use a neutral gray tint to decrease stimulation of the eye by all wavelengths in the visible spectrum. We will compare this intervention to a thin-film spectacle coating designed to specifically block 480-nm light. The gray tint will decrease both direct and indirect stimulation of the IPRGCs by blocking all wavelengths of the visible spectrum. The 480-nm thin-film will specifically target direct stimulation of the IPRGC.

All tints and thin films will be calibrated such that the optical density, that is the overall "darkness" of all study lenses, will be the same. All study lenses will appear to have the same overall light blocking effect to study subjects. The lenses are intended to be a preventative or prophylactic treatment for migraine.

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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	University of Utah	Bradley Katz	Yes	

   a. **Select the lead site. Select N/A if there is no lead site.**

   ☑ **N/A**

   Explain:

   The University of Utah is the lead site

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
View	AXON OPTICS, LLC	Industry	Bradley Katz, CED Axon Optics, LLC 1225 E 700 S SLC, UT 84102 801-230-4851		

4. **Does this study have functions assigned to a Contract Research Organization (CRO)?**

   ● **Yes** ○ No

   a. **Provide CRO Contact Information:**

   ECommunity Research, LLC, c/o Yaira Garzon, 55 NW Chaucer Ln, Boca Raton, Florida, 33432
   Phone 985-429-1139
   Fax 561-362-9598
   Cell: 617640-2711

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:**
   University of Utah

2. **Site Principal Investigator**
   ☑ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   Bradley Katz

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

   a. **Position of the Site Principal Investigator**
   Faculty or Non-Academic Equivalent

   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
Susan Bracken	sbracken@hsc.utah.edu	3/31/2018 MCG
YAIRA GARZON	YAIRA.GARZON@ECRESEARCH.ORG	G
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/10/2017 MC
Elizabeth Nuttall	Elizabeth.Nuttall@hsc.utah.edu	3/3/2017 MCG
Samuel Taylor	u6011742@utah.edu	1/28/2020 MG

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

Name	Email	Training	Obtaining Consent	CoI Date
Susan Baggaley	susan.baggaley@hsc.utah.edu	3/7/2019 SMG	☐	11/8/2019
Steve Blair	blair@ece.utah.edu	1/2/2018 MG	☐	11/25/2019
Susan Bracken	sbracken@hsc.utah.edu	3/31/2018 MCG	☑	10/23/2019
Kevin Brennan	K.C.Brennan@utah.edu	6/18/2019 MG	☐	9/19/2019
Kathleen Digre	kathleen.digre@hsc.utah.edu	3/20/2018 MCG	☐	1/16/2020
Barbara Hart	barbara.hart@hsc.utah.edu	3/16/2017 MCG	☑	5/1/2019

Name	Email	Training	Obtaining Consent	CoI Date
Elliot Nielson	elliot.nielson@hci.utah.edu	1/4/2018 MCG	☐	8/22/2018
Karly Pippitt	karly.pippitt@hsc.utah.edu	5/19/2019 MG	☐	11/4/2019
Samuel Taylor	u6011742@utah.edu	1/28/2020 MG	☑	3/25/2019

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:**

Recruitment

Consent/Enrollment

Research observation/intervention with participants

Data collection

Data analysis

Do you have an enrollment goal or anticipated enrollment number for this site?

- ○ Yes
- ○ No

8. **Select the University of Utah department responsible for this research:**
OPHTHALMOLOGY

9. **Add any additional sites that are part of this performance group**
There are no items to display

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Sponsor Information

Please review these previously entered fields as you fill out the new form:

Sponsor: AXON OPTICS, LLC
Contact: Bradley Katz, CED Axon Optics, LLC 1225 E 700 S SLC, UT 84102 801-230-4851

a. Are you receiving award or contract management for the sponsored funds through the University of Utah Office of Sponsored Projects?

● **Yes** ○ No

If yes, select the associated OSP Proposal ID/DSS through eAward to link it to the ERICA system.

You must have a fully approved Proposal ID/DSS number through eProposal which will show up in eAward after OSP has integrated the ID. To access the eAward application, use the instructions on the OSP website.

Link to a Proposal ID/DSS through eAward

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3. Participants

1. Ages of Participants:

18 and older (Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):
between ages of 18 and 80 inclusive

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: 140

At Utah prior to October 2019: 20

5. Characteristics of Participants/Inclusion Criteria:

For inclusion, subjects must meet the International Headache Society criteria for chronic migraine (International Classification of Headache Disorders, 3rd edition (Headache Classification Committee of the International Headache Society, 2013; Figure 1A) - OR - subjects must meet the International Headache Society criteria for episodic migraine (Headache Classification Committee of the International Headache Society, 2013; Figure 1B) AND have at least 8 headache days per month ("high-frequency episodic migraine"). All subjects must be between the ages of 18 and 80 years-old.

To be included in the study, in the best judgment of the investigator, subjects must be stable on their current migraine treatment regimen. Stability is defined as no major changes in therapy contemplated within the next 4 months.

Subjects should be on a stable course of all prescription medications for the 4 weeks preceding enrollment.

6. Participant Exclusion Criteria:

Subjects with other light sensitive conditions, such as iritis and blepharospasm, will be excluded. Subjects with best-corrected visual acuity less than 20/40 will be excluded. Subjects with diseases of the retina, such as diabetic retinopathy and macular degeneration will be excluded. Subjects using medications known to affect the eye will be excluded (e.g. chloroquine, hydroxychloroquine, ethambutol, amiodarone). Due to constraints on the manufacture and mounting of study lenses into study frames, the study must exclude subjects who are very nearsighted (more than 4 diopters), subjects who are very farsighted (more than 2 diopters), and subjects who have more than 2.5 diopters of astigmatism.

Because of the cyclical effects of botulinum toxin injections and other nerve blocks, patients undergoing these treatments will be excluded. Subjects must not have had any injections or blocks within 4 months of enrollment and should not receive any further blocks until they exit the study.

Subjects with *continuous daily* headache (a headache frequency of 100%) will be excluded. Subjects who do not have a headache frequency of at least 8 days per month will be excluded.

Subjects with medication overuse headache will be excluded (Figure 1C). A patient with a history of medication overuse who has not overused abortive medications for the past 4 months can be included.

Subjects who abuse alcohol or use illicit drugs will be excluded.

Subjects may continue to use their customary preventative, abortive or rescue medications for migraine throughout the trial.

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

○ Yes ● **No**

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4. Study Information

1. **Design of Study (select all that apply):**
   Prospective Clinical Research
   Randomized
   Other

   If Other, describe:
   Active control

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

3. **Length of entire study, from initiation through closeout:**
   30 months

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.)

   Referrals

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

   From a database or participant pool for which participants have given prior permission to be contacted for research studies

   Other

   A website has been created for recruitment purposes. This website has been optimized such that internet search engines looking for information about migraine or light sensitivity will be able to identify the site. www.migraineglassesstudy.com.

   A 45-second recruitment video has been developed to aid recruitment and is embedded in the website.

   The website has a questionnaire embedded that potential participants may complete. This questionnaire will help potential participants determine if they meet the inclusion and exclusion criteria; the completed questionnaire will be forwarded to the clinical coordinator at the site closest to the potential participant.

   This study can also be found by individuals searching the ClinicalTrials.gov website.

   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.):**

   Physicians treating patients for migraine will ask potential subjects if they might be interested in participating in the research. If patients agree, they will be contacted by a study coordinator who will give them additional information about the study and determine eligibility. If still interested, subjects will be invited to participate.

   A recruitment letter may be sent to patients who have been seen in the University's headache clinic.

   The recruitment video will be posted on the Moran Eye Center's Facebook page and "blasted" to Facebook subscribers who live near any of the study sites and who have mentioned "headache", "migraine", or "light sensitivity" on their Facebook page.

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.**

Each subject will be randomized to receive spectacles treated with either a thin-film coating or a conventional tint. The conventional tint will serve as an “active control”. In an effort to keep subjects masked to the intervention to which they’ve been assigned, subjects will be told that both tints and thin films have been shown to improve headaches and that the purpose of the study is to determine if thin films or tints are more effective. Subjects will not be informed that there is a “control”, “placebo” or “sham” intervention.

Subjects will be told that the lenses are to be used to reduce the frequency and severity of headaches and their impact on daily activities. Accordingly, during the intervention period, subjects will be instructed to wear their spectacles during all waking hours.

Subjects who do not wear glasses will be given study spectacles without any optical correction. Subjects who already wear glasses will be given customized spectacles that incorporate their optical correction. Subjects who customarily wear contact lenses will be asked to wear glasses without an optical correction over their contact lenses.

The optical properties of the thin film coating and the gray tint are shown in Figure 2. All spectacles will have the same overall optical density across the visible spectrum. This statement means that all study eyewear will appear to have the same amount of “darkness” to the subject. The total study duration will be 16 weeks

Table 1. Protocol Visit Schedule

Visit	Week	Activities
1	0	Determine eligibility
		Informed Consent
		HIT-6
		Baseline photophobia and ADL questionnaire
		Receive diary
		Randomization
2	4	Diary check
		HIT-6
		Receive glasses/Check glasses fit
3	8	Diary check
		HIT-6
		Check glasses fit

4	12	Diary check
		HIT-6
		Check glasses fit
5	16	Diary check
		HIT-6
		Final photophobia, ADL and masking questionnaires
		Keep glasses OR receive compensation and return glasses

Baseline Visit 1 (Week 0)

Subjects who meet study inclusion and exclusion criteria will be invited to participate in the study. Potential subjects will have all of their questions about the study answered. Subjects who agree to participate will sign an informed consent document and be given a copy of the document. They will fill out a baseline questionnaire regarding light sensitivity and activities of daily living (Figure 3). They will complete the 6-item Headache Impact Test (HIT-6; Figure 4) The HIT-6 is copyrighted, but its use is not restricted by the holder of the copyright and it's not necessary to get permission or pay the copyright holder for use of the questionnaire. At the discretion of the site PI or coordinator, this visit may be completed by phone. Study materials including the informed consent document and questionnaires may be transmitted by U.S. mail, email, or fax.

Subjects will be randomized with equal allocation to receive either tinted or thin-film coated spectacles. A random permuted block randomization will be employed. However, before receiving their study spectacles, subjects will complete a four-week “baseline period” during which no study lenses will be worn. This period will help establish the base-line characteristics of their headaches. Subjects will keep daily diaries throughout the 16-week study detailing the frequency and severity of their headaches (Figure 5).

Visit 2 (Week 4)

When subjects return after the 4-week baseline period, the research team will review their diaries. Subjects must provide at least 20 days of diary data and must have had at least 15 headache days (defined as a calendar day consisting of at least 4 hours of continuous headache). This requirement helps insure subjects meet the definition of chronic migraine. Subjects must have had at least 4 distinct headache episodes each lasting at least 4 hours during the 4-week baseline period. This requirement helps insure that subjects with continuous headache are not included in the study, as these subjects are often unresponsive to any headache treatments. Subjects whose diaries do not meet these criteria will exit the study. Subjects whose diaries indicate that they are overusing abortive pain medications will exit the study. Subjects who exit the study at this point will be given a $25 gift card. At the discretion of the site PI or coordinator, this visit may be completed via phone. Study instruments including the diaries and questionnaires may be completed by phone or transmitted by U.S. mail, email or fax. Alternatively, these instruments may also be completed by the participant within REDCap.

Subjects whose diaries meet these criteria will complete a questionnaire and receive their study spectacles. The research team will insure the glasses fit comfortably and will instruct the subjects to wear them full time. Subjects will receive new diaries.

Visit 3 (Week 8)

The research team will review the subject’s diaries, insure the subject’s glasses still fit comfortably, and will instruct the subject to continue to wear the glasses full-time. Subjects will complete a questionnaire and receive new diaries. At the discretion of the site PI or coordinator, this visit may be completed via phone. Study instruments

including the diaries and questionnaires may be completed by phone or transmitted by U.S. mail, email or fax. Alternatively, these instruments may also be completed by the participant within REDCap.

Visit 4 (Week 12)

The research team will review the subject's diaries, insure the subject's glasses still fit comfortably, and will instruct the subject to continue to wear the glasses full-time. Subjects will complete a questionnaire and receive new diaries. At the discretion of the site PI or coordinator, this visit may be completed via phone. Study instruments including the diaries and questionnaires may be completed by phone or transmitted by U.S. mail, email or fax. Alternatively, these instruments may also be completed by the participant within REDCap.

Visit 5 (Week 16)

At the final visit, subjects will turn in their diaries. Subjects may elect to keep their study glasses or receive a $100 gift card. Subjects will complete a final light sensitivity and activities of daily living questionnaire (Figure 6) and a masking questionnaire required by FDA (Figure 7). For long-term follow-up, subjects will be asked if they may be contacted at 6 and 12 months after the completion of the follow-up period to determine if they are still using the study lenses. At the discretion of the site PI or coordinator, this visit may be completed via phone. Study instruments including the diaries and questionnaires may be completed by phone or transmitted by U.S. mail, email or fax. Alternatively, these instruments may also be completed by the participant within REDCap.

Study coordinators will contact subjects by telephone once between each study visit to insure they are completing their diaries and wearing their study-related spectacles. These weekly contacts will also enable coordinators to identify and address any barriers to adherence with the protocol. These contacts will help maximize retention and minimize loss to follow-up. The Week 8 and Week 12 visits are intended to help with subject retention and to insure subjects are completing their diaries.

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.**

Preliminary Analyses

Baseline characteristics will be summarized by randomized treatment group with standardized differences between treatment groups used to assess the balance of patient characteristics between the two groups. Univariate summaries will also be performed at baseline and follow-up for the primary and secondary outcome variables. If quantitative outcome variables exhibit substantial skewness, transformations may be sought to better approximate normality.

Primary Analysis of Headache Days

The primary analysis of the efficacy of the thin-film intervention will be conducted as an analysis of covariance comparing the proportion of days during the 12 week follow-up period recorded as headache days between the thin-film treatment group and the tinted glasses group, using the proportion of headache days during the 4-week baseline as a covariate. The null hypothesis of no treatment effect on headache frequency will be rejected if the 2-sided p-value corresponding to the treatment effect is smaller than 0.05.

In a secondary analysis, generalized estimating equations (GEE) will be applied to a generalized linear model in which the probability of reporting a headache day during the treatment period is related to a) the baseline frequency of headache days, b) the randomized treatment group, c) week of follow-up, defined as a categorical variable, and d) the interaction of the randomized treatment group with follow-up week. This analysis will be used to characterize the treatment effect over different portions of the follow-up period. A binary outcome model with a logistic link function will be used. A compound symmetry working covariance matrix will be applied and robust standard errors will be used for statistical inferences. The analysis will provide estimates of the odds ratio (with associated 95% confidence intervals and p-values) for reporting a headache day between the two treatment groups obtained separately for each follow-up month. If the interaction between the randomized treatment group and week of follow-up is not statistically significant at the $\alpha=0.05$ level, an overall estimate of the odds ratio for reporting a day with severe headache between the two treatment groups will be provided under a reduced model which excludes the randomized treatment group by follow-up week interaction. For reporting purposes, we will

also provide ratios of the probabilities for reporting headache days using a marginal means approach, with bootstrap resampling used to estimate 95% confidence intervals and p-values.

Analysis of HIT-6

The main secondary analysis of the HIT-6 Total Score will be performed used a linear mixed effects model for a normally distributed outcome. The mixed effects model will relate the mean HIT-6 scores at weeks 4, 8,12, and 16 of treatment to a) the baseline (week 0) HIT-6 score, b) the randomized treatment group, c) the follow-up visit, defined as a categorical variable, and d) the interaction of the randomized treatment group with follow-up visit. An unstructured covariance model will be used to account for repeat observations over the three follow-up assessments. The main contrast to evaluate the treatment effect will compare the mean HIT-6 scores over the 4, 8, 12 and 16 week visits; additional exploratory contrasts will compare the HIT-6 scores at weeks 4, 8, 12, and 16 individually.

Sample Size and Power

In a subgroup of 22 subjects with at least 50% and less than 100% headache days in our pilot crossover trial, the pooled mean ± standard deviation for the follow-up % of headache days across the two periods was 69.0% ± 18.6%. We observed a Pearson correlation of 0.55 between the baseline and follow-up % of headache days. Assuming the same means and standard deviations, and allowing for 10% loss-to-follow-up, 140 randomized subjects (70 for each treatment group) will provide 80% power with 2-sided α=0.05 to detect a mean reduction in the % of headache days of 7.8%. This would represent, for example, a decrease from 69.0% headache days to 61.2% headache days.

The effect size of 7.8% is under half the assumed follow-up standard deviation of 18.6% points, and thus represents a moderate effect size.

Other Secondary Outcomes

To measure severity of headaches, we will use the subjects' daily diaries to count the number of days with headache that either a) made activity difficult, b) caused activity changes, or c) caused patient to go to bed. We will compare the proportion of days that are free of headaches leading to any one of these three criteria using the same GEE approach that was described for the sensitivity analysis of the frequency of headache days.

Exploratory Outcomes

a. Proportion of subjects who were able to move out of the "very severe impact" category of the HIT-6 between baseline and the three follow-up assessments.

b. Proportion of patients who experienced at least a 5-point improvement in their HIT-6 score from baseline to each of the three follow-up assessments (weeks 8, 12, and 16).

c. Proportion of days that are free of headaches that require use of medications to control the headache over the 12-week intervention.

d. Proportion of days with light sensitivity over the 12-week intervention.

e. Average Number of Hours Slept per night over the 12-week intervention.

Subject participants ages 18-22 years ("transitional adolescents")

We are interested in the comparative effectiveness of tints and coatings in the treatment of migraine within this age group. Enrollment and randomization will be stratified within this age group to allow a statistical analysis for this subgroup. Subjects in this age group will have a separate block randomization. Based on previous experience, we anticipate enrolling 6-8 subjects in this age group

Analysis Plan for Secondary and Exploratory Outcomes

Outcomes defined as proportions of days meeting designated criteria based on diary information. Analyses of secondary and exploratory outcomes defined by proportions of days during the follow-up period that satisfy designated conditions will be carried out using the same GEE approach that was described for the secondary analysis of the proportion of headache-free days. Thus, for each outcome, we will estimate the treatment effect separately during each of the four follow-up months as well as the overall effect across all 4 follow-up months.

Numeric outcomes. Descriptive summaries and graphical displays using histograms will provide numeric outcome variables at baseline and over the respective follow-up assessments, by treatment group. Transformations may be sought to better approximate normality for outcomes exhibiting substantial skewness. Numeric secondary and exploratory outcomes that are assessed at baseline and the week 4, week 8, week 12 and week 16 follow-up visits will be analyzed using the linear mixed effects modeling approach described for the HIT-6 score.

Multiple comparisons. Both the primary and the main secondary outcomes will be compared between the randomized groups using a 2-sided α-level of 0.05. Additional secondary and exploratory outcomes will also be compared between the treatment groups using a 2-sided α level of 0.05, without adjustment for multiple comparisons. However, all results from these analyses will be interpreted as exploratory and will take into account the risk of Type 1 errors resulting from multiple hypothesis tests.

Missing Data. The computation of the % of headache days will include only those days with non-missing headache diary information. This analysis will remain approximately unbiased as long as the days on which headache status is recorded in the diaries are independent of actual headache status. The analysis of the HIT-6, which is based on a linear mixed effects model, will be approximately unbiased so long as the pattern of missing data is missing at random, meaning that the probability that an outcome measurement is missing may depend on the values of other non-missing measurements, but not on the value of the missing measurement itself. If the fraction of missing HIT-6 scores exceeds 10% at any given follow-up visit, multiple imputation will also be applied prior to the analysis of the main secondary HIT-6 outcome.

Interim Analysis.

No formal interim analyses for efficacy will be performed.

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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):**

Susan Bracken	University of Utah
Barbara Hart	University of Utah
Samuel Taylor	University of Utah

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

Last Name First Name Affiliation
Friedman Deborah University of Texas - Southwestern, Dallas, TX
Halker Singh Rashmi Mayo Clinics, Phoenix, AZ
Clark Kelly Mayo Clinics, Phoenix, AZ
Rosen Noah Hofstra University/Northwell Health, Great Neck, NY
Eng Melissa Hofstra University/Northwell Health, Great Neck, NY
Rizzoli Paul Harvard University/Brigham and Women's Hospital, Boston, MA

2. **Describe the location(s) where consent will be obtained.**
Consent will be obtained in a private examination room or by phone. If the consent process is conducted by phone, a hard copy of the consent form will be sent by U.S. mail, email, or fax. Alternatively, it may be possible in the near future for participants to sign the consent form electronically within REDCap.

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).**
Subjects will be given the opportunity to discuss the study with friends and family before giving consent. Otherwise, consent will be obtained immediately; there will be no waiting period. Subjects will be informed they may withdraw at any time if they change their mind.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
Persons obtaining consent will emphasize to participants that participation is strictly voluntary. Persons obtaining consent with emphasize to participants that they may discuss the study with friends and family before giving consent.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
The person obtaining consent will ask potential subjects if they'd like more time to think about participation or if they'd like the opportunity to discuss participation with family or friends.

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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PI: Bradley Katz M.D., Ph.D. **Submitted:** 3/29/2016

Title: Spectacle Tints and Thin-Films to Reduce Headache Frequency in Patients with Migraine

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

   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

   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

   Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

   Other additional details (specify):

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

   Select all that apply:

   Study Monitor or Contract Research Organization (CRO)

   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.)?**
Study data and documentation monitoring will take place at each site after 5 subjects have been enrolled, after 10 subjects have been enrolled, after 15 subjects have been enrolled, after 20 subjects have been enrolled, and at closeout.

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Safety Monitoring Plan

1. **Describe the safety monitoring entity for this study:**

   a. **Select all that apply:**

   Principal Investigator

   Please specify:

   b. **Describe the expertise and affiliation of the individual(s) selected above who will monitor the study:**

   Dr. Katz is a board-certified ophthalmologist and University of Utah physician.

2. **Describe the data and events that will be monitored and reviewed (e.g., vital signs, safety blood labs, depression scales, neurological exams, types of adverse events, etc.):**

   Serious adverse events, defined as events related to the Trial that result in a participant being injured, being evaluated in an emergency room, admitted to a hospital, or death, shall be reported to the Sponsor by phone within 24 hours of the CRO's knowledge of the event.

   Serious adverse events that are deemed by the Site Investigator not to be related to the Trial will be reported to the Sponsor on a quarterly basis, by written report from the CRO.

   Adverse events that are not serious will be reported to the Sponsor on a quarterly basis, by written report from the CRO.

3. **Describe the types of reports that will be produced by the monitoring entity (e.g., safety, study progress, interim analysis, etc.):**

   Safety reports will be produced each quarter. There will be no study progress reports or interim analyses.

4. **Describe the specific triggers or stopping rules for the study:**

   a. **Under what conditions will a participant be withdrawn from the study?**

   A subject can always voluntarily withdraw.

   At the 4-week visit, a member of the research team will review the diary entries for the past 4 weeks. Subjects who have a headache frequency less than 50% will be withdrawn. Subjects who have a headache frequency of 100% will be withdrawn.

   The site investigators or principal investigator may withdraw a participant for the following reasons:

   1) Failure to attend scheduled follow-up appointments

   2) Failure to complete diaries or other study instruments

   3) Failure to comply with study guidelines

   b. **Under what conditions will the study be modified or stopped?**

   There are no plans to modify the study. A similar previous study was completed at the University (IRB #47263) and no adverse events occurred.

   There are no plans to stop the study. As it is minimal risk, conditions for stopping the study have not been established.

   The Sponsor reserves the right to temporarily suspend or prematurely discontinue this study either at a single site, multiple sites, or at all sites at any time for reasons including, but not limited to, safety or ethical issues, inaccurate or incomplete data recording, noncompliance, or unsatisfactory enrollment with respect to quality or quantity. If the study is prematurely terminated or suspended, the Sponsor (or its representative) will inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension, in accordance with applicable regulatory requirement(s). The IRB will also be informed and provided with reason(s) for the termination or suspension by the Sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s). In addition, arrangements will be made for the return of all unused investigational products and other material in accordance with the Sponsor's procedures for the study.

5. **How often will the data and events be reviewed by the monitoring entity (e.g., after every 5 submits, monthly, quarterly, twice a year, etc.)?**
   Data and events will be monitored annually

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6. Risks and Benefits

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

Because a similar study was conducted at the University without any adverse events, we do not anticipate any significant risks in the current study.

Subjects who don't already wear glasses may find wearing glasses uncomfortable. The PI has made every attempt to choose glasses that are lightweight and comfortable. The PI has also arranged for each site to have a companion optical shop available to adjust the frames for maximum comfort.

There is a risk that participants will not experience any improvement in their headaches. None of the subjects in our previous study reported an exacerbation of their headaches during the study.

There is a risk of loss of confidentiality.

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

In our previous study, a majority of subjects had statistically significant reductions in the headaches. If successful, these spectacle coatings may be the first FDA-approved treatment for migraine that specifically addresses light sensitivity. Based on our previous study, it is expected that most subjects in both arms of the study will experience at least some reduction in their light sensitivity. Results from this study will help other migraine patients determine if spectacle tints and/or thin-films might be beneficial to them.

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:

Subjects who complete the entire study will choose to either keep their study glasses or receive a check for $100.

Subjects who complete the first 4 weeks of the study, but who are withdrawn because they no longer meet inclusion/exclusion criteria at the 4-week visit will receive a check for $25.

b. Specify when participants will be paid (e.g. at each visit, at end of study, etc.):
As above.

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):
Not applicable

d. If applicable, explain plan for prorating payments if participant does not complete the study:
Payments will not be prorated except as stipulated, above.

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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

   Waiver or Alteration of Authorization

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

   To whom?
   FDA

   And for what purposes?
   The FDA may request an audit of the data if they are used to request a labeling indication as a treatment for migraine.

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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Request for Waiver or Alteration of Authorization

Request for Waiver of Authorization for Recruitment Only

This option must only be used if you are reviewing PHI in order to identify eligible participants BEFORE approaching them to obtain consent and authorization. All other waiver requests must be entered below.

Waiver of Authorization for Recruitment Requested

Other Requests for Waivers of Authorization:

- *Click "Add" below to add a new waiver request to this application.*
- *Click the waiver name link to edit a waiver that has already been created.*
- *To delete a waiver request, contact the IRB.*

Date Created	Type of Request	Purpose of Waiver Request
There are no items to display		

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Request for Waiver or Alteration of Authorization

Request for Waiver of Authorization for Recruitment Only

The PI must agree to the terms of this waiver request as described on this page. When the PI uses the "Submit" activity to submit the application for IRB review, a checkbox to accept the terms will be available in the "Submit" activity window.

This waiver request includes justification for waivers of consent for recruitment only, according to 45 CFR 46.116(d).

Terms for the Waiver of Authorization:

- The purpose of this waiver of authorization is to allow for the use of PHI in order to identify and recruit individuals who may be eligible to participate in the specific research described in this IRB application. The waiver of authorization is necessary to accommodate this minimal-risk research activity prior to seeking a full authorization from research participants.
- Methods for identifying individuals may include the following:
  - Reviewing medical charts
  - Reviewing databases that include PHI
  - Reviewing other medical- or health-based documents that include PHI
- Identifiable information used under this waiver may include the following, as this is the minimum necessary for identifying eligible individuals:
  - Name
  - Contact information, such as phone number, address, or email address
  - An ID number, such as MRN or SSN
  - Date of birth
  - Medical and health information that may determine study eligibility
- Any PHI recorded by the study team will only be used for recruitment and determining study eligibility. After this has been completed, the PHI must be removed from the research record or destroyed, unless the participants have given authorization for continued use of the PHI.
- PHI will only be viewed by approved members of the study team and will not be disclosed for research purposes to any individual or institution without the participants' authorization for such use and disclosure of the PHI.
- PHI will be stored in a secure manner according to HIPAA privacy and security provisions.

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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.
The following label will be affixed to the inside of case for the glasses:
Axon Optics, LLC, Salt Lake City, UT, USA
CAUTION: Investigational device. Limited by Federal law to investigational use. Not suitable for night driving.

Thin film coatings for spectacles are similar in design to anti-reflective coatings commonly dispensed for prescription and cosmetic eyewear. Anti-reflective coatings may be purchased without a prescription. There are no known risks to subjects from anti-reflective or other thin-film coatings. In a previous study of thin-film coatings and migraine, there were no adverse effects of the coatings. The tinted spectacles used in this study will be similar to non-prescription eyewear one could purchase without a prescription. However, because the study lenses are part of an investigational medical device study, all spectacle frames that contain study lenses will be numbered and stored in a locked cabinet. Only the research team at each site will have access to lenses and the research team will use an Excel log to track the location of all study 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.**
Spectacle lenses are considered to be 510(K) exempt according to this page from FDA: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=HQG (accessed 20-March-2018). The product classification and the page from CFR 21 are attached to this application.

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8. Resources and Responsibilities

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

The principal investigator will be responsible for the design and execution of the study. The PI is a board-certified ophthalmologist and has been responsible for the safe conduct of other trials at the University. He has completed all required CITI training.

Site Investigators will be responsible for subject recruitment and the the safe conduct of the study at each site. All investigators will be board certified or board eligible neurologists, familiar with the treatment of migraine and other headache disorders..

Site Study Coordinators will be responsible for insuring that subjects meet all inclusion and exclusion criteria, that subjects provide informed consent, that subjects complete all study instruments and that subjects comply with the study protocol. They will also be responsible for data entry and maintenance of subject and regulatory binders. They will be responsible for reporting adverse events.

The CRO will be responsible for qualifying study sites, and periodically auditing the sites for compliance with study protocol.

The CRO will insure that all site personnel have undergone appropriate training for their role, that they've completed appropriate training in the safe conduct of human clinical research, and that they have completed appropriate training in good clinical practice.

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:**

The PI at each site will be asked to sign the protocol document indicating that they have read, that they understand, and that they will comply with the protocol.

The CRO or Dr. Katz will conduct a teleconference with the research team at each site before they begin enrollment to insure they understand the protocol and to answer questions they may have about study procedures.

The CRO will maintain a training log that documents that the research team at each site has completed appropriate training in the conduct of human research.

The CRO will conduct periodic audits of each site to insure that regulatory binders are up-to-date.

3. **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**

All research activities will be conducted at an outpatient clinic.

Other sites collaborating in this research include:

Mayo Clinics, Scottsdale, AZ. Site PI: Dr. Rashmi Halker-Singh

Northwell Health/Hofstra University, Great Neck, NY. Site PI: Dr. Noah Rosen

Brigham and Women's Hospital/Harvard University, Boston, MA. Site PI: Dr. Paul Rizzoli

University of Texas Southwestern, Dallas, TX. Site PI: Dr. Deborah Friedman

Each of these sites are governed by their local IRB.

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.**

All subjects will already be under the care of a physician for their headaches. Because the study is not anticipated to incur any additional risk to subjects, no specific additional resources will be made available to subjects.

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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

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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.**

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uTRAC

University TRAcking of Clinical research (uTRAC)

All prospective clinical research studies conducted at the University of Utah must complete a uTRAC application prior to IRB approval and the initiation of research procedures. Based on the responses provided in your IRB application, a uTRAC application is necessary for this study.

For more information about uTRAC and the requirements, please contact the Clinical Research Compliance and Education (CRCE) Office at:
Phone: 801-213-3601
Email: utrac-support@umail.utah.edu
Website: https://pulse.utah.edu/site/comser/clreco

If you do not have a uTRAC account, please have your department's account requestor request one. If you are unable to locate an account requestor please contact uTRAC support utrac-support@umail.utah.edu.

Instructions:

1. **If you have already created a uTRAC application, click the Select button below to link the trial to the ERICA application.**
2. **If your study has been given an exemption from the CRCE office, please attach it where indicated below.**

Clinical Trials:

Link	PI	Title
FP00007362	Katz	Spectacle Tints and Thin-Films to Reduce Headache Frequency in Patients with Migraine

CRCE Exemption Attachments:

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