Cover Page

Topo-guided LASIK and Photorefractive Keratectomy vs Wavefront LASIK and Photorefractive Keratectomy

PI: Mark Mifflin, MD

NCT 03075176

IRB # 95434

Document date: 12/9/2021 (most recent IRB approval)

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IRB_00095434 **Created:** 8/25/2016 10:07 AM

PI: Mark Mifflin M.D. **Submitted:** 10/25/2016

Title: Outcomes of topography-guided laser-assisted in situ keratomileusis (LASIK) and phororefractive keratectomy (PRK) compared to wavefront optimized LASIK and PRK

1. Study Introduction

1. **Responsible Investigator:**
   Mark Mifflin

Email	Training	CoI Date
mark.mifflin@hsc.utah.edu	6/12/2020 MCG	10/12/2022

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	2/24/2020 MCG
Colin Ip	colin.ip@hsc.utah.edu	5/22/2021 MG
Donald Jones	kyle.d.jones@hsc.utah.edu	6/21/2021 MG
Amy Lin	amy.lin@hsc.utah.edu	4/3/2021 MCG
Elizabeth Nuttall	Elizabeth.Nuttall@hsc.utah.edu	2/4/2020 MCG

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

Last Name	First Name	E-Mail
church-livingston	myrna	myrna.church@hsc.utah.edu

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

5. **Title Of Study:**
   Outcomes of topography-guided laser-assisted in situ keratomileusis (LASIK) and phororefractive keratectomy (PRK) compared to wavefront optimized LASIK and PRK

6. **Study Purposes and Objectives:**

Hypothesis: Snellen uncorrected distance visual acuity will be the same with wavefront optimized LASIK/PRK treatment compared to topography guided custom ablation LASIK/PRK treatment.

Objectives: We aim to conduct a prospective trial comparing the post-operative outcomes in fellow eyes, one of which has undergone wavefront optimized LASIK or PRK treatment and one of which has undergone topography guided LASIK or PRK in order to determine whether equivalent patient visual outcomes are achievable at our institution using both forms of LASIK or PRK treatment.

The outcomes we will measure include uncorrected visual acuity.

7. **Is this a multi-site study, where more than one site needs IRB approval?**

○ Yes ● **No**

8. **Background and Introduction:**

In photoablation procedures, an excimer laser is used to sculpt corneal tissue to correct refractive error. During LASIK, a flap of corneal tissue is first created with a femtosecond laser and then the excimer laser is used to ablate the corneal stromal tissue beneath the flap allowing for rapid healing time and visual recovery in addition to a reduction in postoperative pain. In PRK the surface layer of epithelium is removed and then the stromal bed is ablated using the same excimer laser as in LASIK.

The change in shape in the cornea induced by traditional ablation corrects lower order aberrations (LOAs) such as spherical and cylindrical refractive errors or near/far sightedness and astigmatism. Other optical aberrations may be induced by the change in corneal shape associated with the ablation, resulting in light from one point on an object failing to converge onto a single point after passing through the eye's optical system. Following laser refractive surgery for nearsightedness, there is an increase in these optical aberrations that cannot be corrected with spectacles called "higher order aberrations" (HOAs). These higher order aberrations result in degradation of vision and visual phenomena often described as starbursts, haloes, or ghosting of images. This may result in symptoms such as difficulty with night driving, reading, glare and light sensitivity.

To reduce the induction of HOAs, wavefront optimized LASIK/PRK treatments were developed. Wavefront optimized treatments are based on complex optical measurements called aberrometry and have been shown to successfully reduce the number of HOAs using pre-programmed ablation profiles based on population analysis. Wavefront optimized treatments have been FDA approved and widely used for years, including at our institution.

Recently, FDA approval was granted for topography guided custom LASIK and PRK ablation treatments (TCAT). This new type of treatment with the potential to even further reduce HOAs even in very irregular corneas by using a non contact device to establish a map of the corneal surface (corneal topography) in combination with measurements of the pupils. This allows for custom treatments based on measurements conducted on each individual eye.

Wavefront optimized treatments have long been in use at our institution and we have recently acquired the tools for newly FDA approved T CAT treatments using the Allegro Topolyzer (Alcon Surgical, Inc). We propose a prospective comparison of patient visual outcomes after performing wavefront optimized laser refractive surgery in one eye compared to custom topography guided LASIK or PRK in the fellow eye.

References:
1. PerezStraziota CE, Randleman B, Stulting D. Visual acuity and higherorder aberrations with wavefrontguided and wavefrontoptimized laser in situ keratomileusis. J Cataract Refract Surg 2010; 36:437–441.
2. Moshirfar M, Schliesser J, et al. Visual outcomes after wavefrontguided photorefractive keratectomy and wavefrontguided laser in situ keratomileusis: Prospective comparison. J Cataract Refract Surg 2010; 36:1336–1343.
3. Stulting D, Fant BS, and TCAT Study Group. Results of topographyguided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. J Cataract Refract Surg 2016; 42:11–18.
4. Pesudovs K, Garamendi E, Elliott D. The Quality of Life Impact of Refractive Correction (QIRC) Questionnaire: Development and Validation. Optometry & Vision Science. 81(10):769777, October 2004.

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	Mark Mifflin	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	OrgID
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:**
   University of Utah

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

Email	Training	CoI Date
mark.mifflin@hsc.utah.edu	6/12/2020 MCG	10/12/2022

   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
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/24/2020 MCG
Colin Ip	colin.ip@hsc.utah.edu	5/22/2021 MG
Donald Jones	kyle.d.jones@hsc.utah.edu	6/21/2021 MG
Amy Lin	amy.lin@hsc.utah.edu	4/3/2021 MCG
Elizabeth Nuttall	Elizabeth.Nuttall@hsc.utah.edu	2/4/2020 MCG

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

Name	Email	Training	Obtaining Consent	CoI Date
Brett Gudgel	brett.gud@gmail.com	7/4/2020 MG	☑	6/30/2020
Amy Lin	amy.lin@hsc.utah.edu	4/3/2021 MCG	☐	8/20/2022
Eric Weinlander	u0779897@utah.edu	7/7/2020 MG	☑	6/21/2021

5. **Site Guests:**

Name	Email	Training
myrna church-livingston	myrna.church@hsc.utah.edu	

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

Enrollment Number:
400

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

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:**

   18 and older (Consent form needed)

2. **Specific age range of participants (e.g., 7-12 years old, 60+, etc.):**
   21 and older

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:**
   approximately 400

   At Utah prior to October 2019: approximately 400

5. **Characteristics of Participants/Inclusion Criteria:**

   All subjects who are deemed suitable candidates for laser refractive surgery after routine refractive surgery screening will be considered eligible for participation in this study. Subjects must be at least 21 years of age and not pregnant or nursing (due to fluctuations in visual parameters during pregnancy).

6. **Participant Exclusion Criteria:**

   Selection will be consistent with the current standard of care for LASIK or PRK. Any patient who is not a suitable candidate for LASIK or PRK will not be included.

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

   ○ Yes ● **No**

4. Study Information

1. **Design of Study (select all that apply):**

   ☐ **Non-Experimental and/or Descriptive Research Design:**

   There are no items to display

   ☑ **Experimental and/or Interventional Research Design:**

   Prospective Biomedical Intervention or Experiment
   Randomized Trial

   ☐ **Development of a research resource (repositories, databases, etc.)**

   There are no items to display

   ☐ **Other**

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

3. **Length of entire study, from initiation through closeout:**
   3 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 or electronic record review

   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.):**

   Patients requesting refractive surgery will be informed about the study and asked if they would like to participate. Advertisements will also be included on the Moran Eye Center website, Facebook page, and Twitter account, as well as in newsprint.

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.**

   Patients who are interested and eligible to participate in the study will be enrolled and will read and sign the study informed consent prior to surgery.

   Participants will have an in depth discussion with our refractive surgery coordinator regarding refractive surgery. Patients will choose LASIK/PRK surgery based on our standard pre-operative discussion that is provided to all patients. As is standard for laser refractive

candidates, the advantages and disadvantages of LASIK/PRK compared to the other refractive surgical options will be discussed. Following patient selection of their preferred type of refractive procedure they will be randomized as discussed below, and only patients who elect for LASIK/PRK will be included in our study.

Prior to surgery, one eye from each patient will be randomly assigned to receive either Wavefront optimized or Topography Guided treatment. Each patient in the study will have a fellow eye enrolled in the other treatment group. Patients will either receive LASIK treatment or PRK treatment in both eyes but the eyes will be randomized to topography guided or wavefront optimized forms of treatment.

All surgical procedures will be performed according to the standard of care and the surgeons' standard practices. The study outcome measures are standard of care for pre-operative and post-operative evaluation of refractive surgery patients.

The primary outcome measures will be visual acuity at the pre-operative and post-operative and post-operative time points.

Study outcome measures will be evaluated for each treated eye of each subject at each study time point. Additional examinations between study time points may be performed as necessary according to the surgeon's usual care, but will not be considered part of the study data. Patients have a right to withdraw at any time and future medical care will not be influenced by their lack of participation.

If enhancement surgery is deemed necessary and performed during the one-year post-operative period, study data collection will end for that eye at the time of the enhancement. All prior collected data will be included in the statistical analysis.

Eyes will be evaluated with the following standard of care procedures:

- pupil size measured in mesopic format: pre-operative only

- corneal pachymetry: pre-operative only

- uncorrected visual acuity: pre-operatively and post-operative Day 1 (+1 day), Week 1 (+/- 3 days), Month 1 (+/- 10 days), Month 3 (+/- 1 month), Month 6 (+/- 1 month) and Month 12 (+/- 1 month).

- best corrected visual acuity and manifest refraction: pre-operatively and post-operative Month 1 (+/- 10 days), Month 3 (+/- 1 month), Month 6 (+/- 1 month) and Month 12 (+/- 1 month)

Patients will also be evaluated with the following procedures for research purposes only:

Contralateral Eye Survey (developed by Moran Eye Center cornea specialists): post-operative Month 3 (+/- 1 month)

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):

All procedures are considered within the standard of care for laser refractive surgery and will be billed to patients in the usual manner; however, participants will be eligible for a reduced study fee for their surgery and post-operative care. Laser refractive surgery is considered cosmetic surgery and is never billed to insurance. The refractive surgery charge includes standard post-operative examinations up to one year.

If enhancement surgery is deemed necessary during the one-year post-operative period, this will be included based on the patient's initial fee, as is standard of care. Any other costs related to the management of adverse events, or if additional refraction correction is necessary at some time after the one-year postoperative period, will remain the patient's responsibility and are not included in the study surgery fee.

Randomization, data collection and analysis are being done for research purposes only.

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.**

Standard statistics will be calculated and used to describe the two treatment groups in terms of all study variables. Statistics will be compiled for each variable at the study time points listed in the data collection protocol. Patients withdrawn from the study prior to surgery will not be included in the data analysis and will be replaced in the enrollment group. For eyes that require enhancement surgery, only data collected prior to the enhancement surgery will in included in the statistical analysis.

Power calculations for this study are based on similar prospective, randomized contralateral eye laser refractive studies comparing wavefront optimized and wavefront guided treatments. Previously published contralateral eye studies demonstrated statistically significant results for similar endpoints as our study by including in the range of 70-100 patients for each treatment group. To ensure sufficient patient numbers accounting for 20-30% drop out, including patients that may need enhancement surgery and may not be able to complete the study.

References:
1. Sales C, Manche E. One-Year Outcomes from a Prospective, Randomized, Eye-to-Eye Comparison of Wavefront-Guided and Wavefront-Optimized LASIK in Myopes. Ophthalmology. Dec 2013. Vol 120: 12, 2396-2402.

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IRB_00095434
- Consent Process

Consent Process

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

Brett Gudgel	University of Utah
Mark Mifflin	**(PI)** University of Utah
Eric Weinlander	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.**
Mid-Valley ophthalmology clinic
Moran ophthalmology clinic

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).**
Participants will be informed about the study when they present to the clinic for the initial laser refractive surgery consult. Consent may be obtained at that time or when they return for the procedure. There is no specified waiting time.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
Patients will be informed that they do not have to take part in the study and they will receive the same standard of care whether or not they participate.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
Two pre-operative visits will be conducted separated by at least one day. Both of these visits include an in person discussion of the surgical procedure and any research procedures with the refractive surgeon. These visits are required as part of our standard refractive surgery protocol and will allow time to exchange information and answer any questions regarding the study and/or surgery for potential study participants.

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

   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

   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 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

   Other or additional details (specify):

   Other or additional details (specify):
   Study team

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year,**

annually, after N participants are enrolled, etc.)?
After 5 participants are enrolled, then every 6 months.

Safety Monitoring Plan

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

   a. **Select all that apply:**

   Other (specify):

   Please specify:
   There is no formal data and safety monitoring board for this study. All treatments, procedures, and testing being performed in the study are within the standard of care and treatment for LASIK patients. The study does not put study participants at any known increased risk beyond that normally assumed by patients undergoing LASIK or PRK outside the study. The investigators feel that the standard processes for identifying and reporting adverse events (AE) are sufficient to safeguard the well-being of study participants.

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

   The PI and Study Staff are licensed medical providers who have the training and experience necessary to assess patient safety.

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.):**

   The investigators have a nomogram from which they work and therefore have expected vision outcomes for patients on an individual basis. It is routine practice to compare actual with expected outcomes as a quality assurance measure. Should any concerns arise prior to completion of the study, a safety analysis will be conducted immediately.

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

   A Safety report will be produced for each safety analysis conducted.

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

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

   A participant would be withdrawn from the study if they no longer desire to participate or if they are deemed to not be a candidate for refractive surgery.

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

   The study regimen would be modified or stopped if medically appropriate.

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 will be reviewed after the first 5 participants are enrolled and every 6 months following. Adverse events will be reviewed as they occur.

6. Risks and Benefits

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

Risk of randomization: Participants will receive wavefront optimized LASIK or PRK in one eye and topography guided LASIK or PRK in the other eye. Participants may experience different outcomes on each eye. Both types of refractive surgery treatment are FDA approved and clinical trial experience has indicated high quality outcomes from both types of procedures.

There is a risk of loss of confidentiality.

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

This study may not provide direct benefit to participants. We hope this study will help us determine if equivalent patient outcomes are achievable using both FDA-approved forms of LASIK/PRK 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:
All procedures are considered within the standard of care for LASIK/PRK surgery and will be billed to patients in the usual manner, however, participants will be eligible for a reduced fee for their surgery and post-operative care.

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

c. If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):
N/A

d. If applicable, explain plan for prorating payments if participant does not complete the study:
N/A

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**

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:**
   - **Collecting samples of blood, organs or tissues from participants for research purposes;**
   - **Introducing Recombinant or Synthetic Nucleic Acids (e.g. viral vectors, oligonucleotides) or cells containing recombinant nucleic acids (e.g. CAR-T) into participants; OR**

- **Introducing other biological materials (e.g. bacteria, viruses) into participants.**

○ 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 Clinical and Translational Science Institute (CTSI)?**

    ○ Yes ● **No**

    The Clinical Research Center (CRC)?

    ○ Yes ○ No

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		

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.

8. Resources and Responsibilities

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

   The principal investigator is a board certified ophthalmologist who is qualified by training and experience to conduct this study.

   Sub-Investigators are either board certified ophthalmologists or cornea fellows working under the PI's supervision and direction. They are qualified by training and experience to conduct this study.

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:**

   Study staff have completed CITI training and will receive study specific training as appropriate. Staff who obtain informed consent will complete Informed Consent Training available through the RATS program.

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

   The Moran Eye Center and satellite clinics

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.**

   Medical and psychological resources are available at our site if needed.

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

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
Mifflin CV 04.09.2014.pdf(0.01)	0.01	7/14/2015 3:23 PM	7/14/2015 3:23 PM	
MifflinCV11-04-2016.doc(0.01)	0.01	2/21/2017 7:55 PM	2/21/2017 7:55 PM	

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

PI: Mark Mifflin M.D. Submitted: 10/25/2016

Title: Outcomes of topography-guided laser-assisted in situ keratomileusis (LASIK) and phororefractive keratectomy (PRK) compared to wavefront optimized LASIK and PRK

Finish Instructions

Finish Instructions

1. **To view errors, select the "Validate" option at the top-left 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.**