Study Title: 70 versus 110 Degrees Side-cut Angles in Femtosecond Laser-assisted in situ Keratomileusis

NCT Number: NCT03122535

Document Date: 05 July 2018

The following Protocol and Statistical Analysis Plan were in place at the time of study closeout with the IRB. IRB closeout occurred on 05 July 2018.

Electronic
RESEARCH INTEGRITY AND COMPLIANCE
THE UNIVERSITY OF UTAH

Date: Wednesday, December 23, 2020 12:14:41 PM

Print Close

IRB_00074858 **Created:** 6/23/2014 8:21 PM

PI: Mark Mifflin M.D. **Submitted:** 7/28/2014

Title: 70 versus 110 Degrees Side-cut Angles in Femtosecond Laser-assisted in situ Keratomileusis

IRB_00074858
View: 1. Study Introduction

1. Study Introduction

1. **Responsible Investigator:**
Mark Mifflin

Email	Training	CoI Date
mark.mifflin@hsc.utah.edu	6/12/2020 MCG	9/19/2020

a. **Position of the Investigator:**

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

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

Name	Email	Training
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/24/2020 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:**
70 versus 110 Degrees Side-cut Angles in Femtosecond Laser-assisted in situ Keratomileusis

6. **Study Purposes and Objectives:**

Different side-cut angles have been used in Femtosecond Laser-assisted in Situ Keratomileusis (FS-LASIK), but no study has compared the safety and efficacy of 70 and 110 degrees side-cut angles. We aim to conduct a prospective trial comparing 70 and 110 degrees side-cut angles on same patient undergoing FS-LASIK. One angle will be performed on the right eye and the other on the left eye. The study will evaluate uncorrected visual acuity, best corrected visual acuity, intraoperative, and postoperative complications. By performing different side-cut angles on a same individual will allow a direct comparison of outcomes, minimizing confounding variables. Additionally, the LASIK flap will be performed using either the Abbott Medical Optics Intralase femtosecond laser or the Alcon Wavelight FS200 femtosecond laser.

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

8. **Background and Introduction:**

   Laser-assisted in Situ Keratomileusis has become the preferred corneal procedure to correct certain refractive errors. Technological advances have increase the accuracy and precision of current treatments. One of the major advancements in LASIK has been the introduction of Femtosecond Laser technology for flap creation. Several studies have compared microkeratome and femtosecond laser technology, showing superior accuracy and precision of flap dimensions in the latter.

   The Femtosecond Laser technology provides different parameters and settings that can be changed according to the surgeon's preference. One of such parameters is the side-cut angle. Some of the most common side-cut angles used today include 45, 70, 90, and 110 degrees. Previous studies have reported on the visual outcomes of side-cut angles, but head to head comparisons are lacking. Currently, there are no studies comparing the safety and efficacy of the 70 and 110 side-cut angles in FS-LASIK. Information regarding the outcomes and complication rates between these side-cut angles will provide an objective measure that can be used when deciding which one is more suitable in FS-LASIK.

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IRB_00074858
View: 2. Location and Sponsor

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
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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IRB_00074858
View: View/Edit

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	9/19/2020

   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
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/24/2020 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
Ashley Brundrett	ashley.brundrett@hsc.utah.edu		☑	8/25/2017
Christopher Smith	christopherb.smith@hsc.utah.edu		☑	7/12/2017

5. **Site Guests:**

Name	Email	Training

There are no items to display

6. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

7. **Select the study procedures that will be conducted at this site:**
   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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IRB_00074858
View: 3. Participants

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 years 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: 200

At Utah prior to October 2019: 200

5. Characteristics of Participants/Inclusion Criteria:

Subjects who are deemed suitable candidates for bilateral LASIK will be considered elegible for participation in this study. Correction will be distance for both eyes. Patients must be at least 21 years of age.

6. Participant Exclusion Criteria:

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

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

◯ Yes ● **No**

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IRB_00074858
View: 4. Study Information

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.)**

   ☐ **Other**

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

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

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

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

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

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

   Other

   Information will be included on the moran eye center website, moran eye center facebook, and moran eye center twitter account.

   http://healthcare.utah.edu/moran/patient_care/refractive_surgery_lasik/

   https://www.facebook.com/moraneyecenter

   https://twitter.com/MoranEyeCenter

   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.):**

   When patients come in requesting refractive surgery, they are asked if they would like to participate in the study. An advertisement will 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 this study will sign the study informed consent prior to surgery. As is standard for our LASIK cases, they will also be required to watch an informational video, read and sign the “Consent to Have Refractive Surgery” and respond to a brief test concerning its content.

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

All study outcome measures will be evaluated for both eyes at every visit. Patient will be masked as to the treatment they receive in either eye so as not to influence their sunjective responses and visual measurements. Post-operative evaluations will be performed at 1 day, 1 week (± 3 days), 1 month (± 10 days), 3 months (± 14 days), 6 months (± 1 month), and 12 moths (± 1 month). Interim examinations may be performed as necessary according to the surgeon’s usual care, but are not considered part of the study data.

Patients will be discontinued from the study if, on the day of surgery, both eyes cannot be randomized and operated as per protocol. Patients have the right to withdraw at any time and future medical care will not be influenced by their lack of participation.

Patients will be evaluated with the following procedures:

· Manifest refraction (sphere, cylinder and axis): Pre op and post-op months 1 (± 10 days), 3 (± 14 days), 6 (± 1 month), and 12 (± 1 month).

· Uncorrected corrected visual acuity: Pre-op and post-op day 1, week 1, and months 1 (± 10 days), 3 (± 14 days), 6 (± 1 month), and 12 (± 1 month) using the Snellen Eye chart

· Best corrected visual acuity: Pre-op and post-op months 3 (± 14 days), 6 (± 1 month), and 12 (± 1 month).

· Pupil size measured in the dark: Pre-op only

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):

Data collection and analysis are 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.**

Summary statistics will be calculated and used to describe the treatment groups (70 versus 110 degrees side-cut angles) in terms of all study variables: manifest refraction, corrected and uncorrected visual acuity and LASIK system used (FS200 or intralase). Statistics will be compiled for the one week, one month, three month, six month and 12 month time points post operatively. Paired t-tests will be used to analyze the difference of corrected and uncorrected visual acuity obtained by each group at the post-op time points, as well as the average change from pre-op to post op corrrected and corrected visual acuities. In order to provide a statitistically significant beta values, a N number of 200 patients will be needed.

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IRB_00074858
View: 4.2 Consent Process

Consent Process

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

Ashley Brundrett	University of Utah
Mark Mifflin	**(PI)** University of Utah
Christopher Smith	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.**
Moran Eye Center Clinics

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).**
Consent will be obtained following standard of care evaluations that determine if an individual is a candidate for bilateral LASIK surgery. This occurs during a series of pre-operative clinic visits. Signed consent will be obtained prior to surgery.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
Patients are free to have LASIK or other refractive surgery that is appropriate for them with the investigators without participating in the study.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
Several pre-op exams are performed prior to surgery so the patient has multiple opportunities to ask questions and discuss with the surgeons.

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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IRB_00074858
View: 5. Data Monitoring Plan

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):

   Other or additional details (specify):
   Surgery and all study procedures will be performed in private exam areas in the Moran clinics and laser surgery.

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):

   Other or additional details (specify):
   Patient information will be maintained in the confidential medical records in accordance with all applicable regulations. Study specific data will be stored on password protected computers and/or locked cabinets or offices.

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

   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):
sub-investigators

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

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IRB_00074858
View: 6. Risks and Benefits

6. Risks and Benefits

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

Risks to study participants are the same as though for any patient undergoing LASIK refractive surgery, including loss of vision, visual side effects, and over- or under-correction.

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

Evaluation of vision and complications on an individual patient who has undergone 70 degrees side-angle cut in one eye and 110 degrees side-angle cut in the other will afford a greater understanding of the safety and efficacy of using this two common side-cut angulations. There is no direct benefit to participants.

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

● **Yes** ○ No

If yes, specify:
Subjects will be charged the research-discounted price for LASIK ($1200 per eye).

4. Is there any compensation to the participants?

○ Yes ● **No**

a. **If yes, answer the following:**
Specify overall amount:

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

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

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

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IRB_00074858
View: 7. HIPAA

7. HIPAA and the Covered Entity

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

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

   (Consent and) Authorization Document

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

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 Center for Clinical and Translational Science (CCTS)?**

    ◯ Yes ● **No**

    The Clinical Services Core (CSC)?

    ◯ Yes ◯ No

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IRB_00074858
View: 8. Resources & Responsibilites

8. Resources and Responsibilities

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

   Dr Mark Mifflin specializes in the medical and surgical treatment of corneal and anterior segment eye diseases. His expertise includes all types of corneal transplantation, cataract surgery, and vision correction using lasers, intra-ocular lenses, and conductive keratoplasty.

   Sub-investigators are ophthalmology fellows (M.D.s) and will work under the supervision of Dr. Mifflin.

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 investigators have completes the CITI human subjects training. The PI has trained the sub-investigators on the protocol.

3. * **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**
   Physical resources required to implement the study protocol are available at the Moran Eye Center clinics. Clinical care services at the John A. Moran Eye Center include three fully equipped operating rooms, minor procedure rooms, 25 examination rooms, minor procedure rooms, laser suites, an optical shop, and a pharmacy.

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.**
   The investigators will be available to answer any questions or discuss any concerns the participants have, both during study visits, and over the phone. Dr. Mifflin has the expertise and medical resources to handle any medical consequences of the research study appropriately.

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IRB_00074858
View: 9. Documents and Attachments

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
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				

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IRB_00074858
View: 10.4. uTRAC Application - GN3 - Popup

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
FP00005465	Mifflin	70 versus 110 Degrees Side-cut Angles in Femtosecond Laser-assisted in situ Keratomileusis

CRCE Exemption Attachments:

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

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IRB_00074858
View: 12. Finish Instructions

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.**