Institutional Review Board

FWA: 00007392 | IRB: 0004173

IRB Number: 120-14 NCT#: 02923232

Approved: 10/01/2017

Post-Approval Request(s):

Approval Expires: 09/30/2018

Office of Scholarship & Sponsored Projects
2043 College Way | UC Box A-133 | Forest Grove, OR 97116
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Proposal to Conduct Research

Research Review Boards

☒ **Institutional Review Board (IRB)**

Study Title

Ocular Adaptation and Visual Performance for Accommodative Contact Lens

IRB Proposal and Review Type

If you are not sure if your research is considered human subjects research, please use the *Request for Determination of IRB Jurisdiction* checklist available on the IRB website (www.pacificu.edu/irb) before continuing with this form. If needed, submit the *Request for Determination of IRB Jurisdiction* to the IRB at irb@pacificu.edu.

☐ **Request for Exemption**

☒ **Proposal to Conduct Human Subjects Research**

- ☒ Expedited Review
- ☐ Full Board Review

Research Personnel and Contact Information

Personnel #1	
Name **Shun-Nan Yang**	**Role** Principal Investigator
Institution Pacific University	**Program** College of Optometry
Email shunnan.yang@pacificu.edu	**Telephone** 503-352-2852
Scope ☐ Recruitment ☐ Consent Process ☐ Data Collection ☒ Data Analysis (with personally identifiable information) ☒ Data Analysis (de-identified data) ☐ Other: _____	

Personnel #2	
Name **Suan A. Resnick**	**Role** Co-Investigator
Institution Farkas, Kassalow, Resnick and Associates, P.C.	**Program**
Email sresnick525@gmail.com	**Telephone** 212-355-5145
Scope ■ Recruitment ■ Consent Process ■ Data Collection ☐ Data Analysis (with personally identifiable information) ☐ Data Analysis (de-identified data) ☐ Other: _____	

Personnel #3	
Name **Partick Caroline**	**Role** Co-Investigator
Institution Pacific University	**Program** College of Optometry
Email patpacific@aol.com	**Telephone** 503-352-2768
Scope ■ Recruitment ■ Consent Process ■ Data Collection ■ Data Analysis (with personally identifiable information) ■ Data Analysis (de-identified data) ☐ Other: _____	

Personnel #4	
Name **David Geffen**	**Role** Co-Investigator
Institution Gordon-Weiss-Schanzlin Vision Institute	**Program**
Email dig2020@aol.com	**Telephone** 858-455-9950
Scope ■ Recruitment ■ Consent Process ■ Data Collection ☐ Data Analysis (with personally identifiable information) ☐ Data Analysis (de-identified data) ☐ Other: _____	

Personnel #5	
Name **Timothy R. Poling**	**Role** Co-Investigator
Institution Botetourt Eyecare	**Program**
Email tpoling2@hotmail.com	**Telephone** 540-797-2780
Scope ■ Recruitment ■ Consent Process ■ Data Collection ☐ Data Analysis (with personally identifiable information) ☐ Data Analysis (de-identified data) ☐ Other: _____	

Funding and Sponsorship

Funding:

Funding for this study is:

☐ Internal (Pacific University) ■ External ☐ This study is not funded

☐ Other: _____

Be sure to maintain sponsorship records as related to this study. Should this proposal be selected for an internal or external audit, all grant and funding documents will need to be available for review during the audit.

Identify the funding source: (*Only as applicable)

Funding Source #1			
Name of Funding Source **One Focus Vision**		**Address of Funding Source** 8358 Sanctuary Lane Fernandina Beach, FL 32034	
Funding Agency Award Number* N/A	**Award Amount** $30,000.00	**Grant Title*** Ocular Adaptation and Visual Performance for Accommodativ	
PI Listed on the Grant* Shun-nan Yang			
Deadline for Application Letter (as applicable)* N/A	**Start Date of Project*** Dec. 13, 2018	**End Date of Project*** Dec. 13, 2019	

Sponsor:

If this is a clinical investigation, list and describe who is sponsoring this study. Please provide addresses for all sponsors. If the sponsor and funding source are the same, please state as such. If you are conducting a clinical investigation, you are required to list and describe who is sponsoring this study. (If the study is not sponsored, then state Not Applicable.)

Same as the funding source.

Conflict of Interest:

Describe any potential or apparent conflict(s) of interest that may exist. (If the study is neither funded nor sponsored, then state *Not Applicable*.)

The investigators do not benefit from the outcomes of the proposed study, except the funding provided by the Sponsor to the Pacific University and eye clinics associated with this study.

Describe any other potential conflict(s) of interest that may exist.

None.

Payment of Research Participants

Will you be paying your research participants? ■ **YES** ☐ **NO** ☐ **N/A**

Please refer to the Office of Research's website for current practices regarding payment of research participants. You may be required to submit additional documentation to the IRB depending on the source of funding."

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IRB Submission Guidance Document

Study Title

Ocular Adaptation and Visual Performance for Accommodative Contact Lens

Medical Device | Drug Study | Clinical Investigation

Medical Device Information

1. Are you using a medical device in your study that is not the subject of study? The device must be used in accordance with its approved indications, with no modifications (on-label use). ☐ **YES** ■ **NO**

2. Are you studying a medical device in your proposal? If the medical device is the object of study, is not being used in accordance with its approved indications, or has not been cleared for marketing, please select YES. (If other medical devices are also being used in the study, please select both options, but provide only the information regarding the medical devices being studied on the *Medical Device Study* form. ■ **YES** ☐ **NO**

You are conducting a Medical Device Study. Additional information will be required by the IRB. Please provide all required information on the *Medical Device Study* **form.** Additionally, please provide labels, informational brochures or documents, and other information pertinent to the device(s) that will (a) aide the IRB in review of your proposal and/or (b) be made available to participants to reference. Upload these documents as a separate resource on IRBNet.

Drug Study Information

Are you conducting a drug study? ☐ **YES** ■ **NO**

Biologic Information

Are you studying a biologic or other food product for human consumption? ☐ **YES** ■ **NO**

☐ Biologic

☐ Other food product for human consumption

Clinical Investigation

Is this project considered a clinical investigation? ■ **YES** ☐ **NO**

Clinical Investigation Number
NCT02923232

Consent Forms

■ I will be collecting signed Informed Consent.

Complete the *Informed Consent*

☐ I will be submitting a Request to Alter or Waive Informed Consent.

Check all that apply:

- ☐ The documentation of signed informed consent will be waived.
- ☐ Alteration of informed consent documentation (modified consent documents, online *or* anonymous surveys, for instance).
- ☐ Request to waive Informed Consent.

Vulnerable and Non-Autonomous Populations

1. Will you be collecting data from (1) children/minors, people who (2) cannot provide their own consent or (3) have a disability or impairment?)

☐ **YES** ■ **NO**

2. Will you be collecting data from pregnant women? ☐ **YES** ■ **NO**

For non-autonomous individuals, researchers must first obtain permission from the parent or guardian, then informed assent from the potential participant. Please refer to Informed Consent information on the IRB website for additional information regarding the Consent Process, particularly as it applies to Permission and Assent. Based on the answers to these questions, the appropriate forms have been added to the proposal.

Prisoners

Does your research involve prisoners? ☐ **YES** ■ **NO**

HIPAA and FERPA

HIPAA

Will your research be using data covered by the HIPAA Privacy Rule? ☐ **YES** ■ **NO** ☐ **N/A**

FERPA

Will your research be using student education record data protected by FERPA? ☐ **YES** ■ **NO** ☐ **N/A**

Release Documentation

Participant Contact Information

Will you be collecting participant's contact information? ☐ **YES** ■ **NO**

Recording Release

Will your research include an Audio Recording? ☐ **YES** ■ **NO**

Photograph and Video Recording Release

Will your research use photographs or video to collect data? ☐ **YES** ■ **NO**

International Research and Translations

International Research

Will you be conducting research internationally? ☐ **YES** ☒ **NO**

Translation

Will any verbal or written communication with participants be conducted in a language other than English? ☐ **YES** ☒ **NO**

Recruitment and Data Collection

Recruitment

Will you be recruiting participants for your research? ☒ **YES** ☐ **NO**

1) Please place all recruitment materials in <u>one</u> document, as possible, and upload separately on IRBNet.

2) List all recruitment materials that will be attached. Recruitment materials include but are not limited to emails, phone scripts, announcement scripts, posters, handouts, and flyers. You may also include text of emails, verbal scripts, etc. in the recruiting section of the proposal if more appropriate. Please do still indicate recruitment elements below, regardless of submission format.

- ☐ Phone-Call Script
- ☐ Announcement Script
- ☐ Email text
- ☐ Poster
- ☐ Handout
- ☒ Flyer
- ☐ Other (if other, please list all other forms of recruitment below)

Data Collection

1) Place all data collection materials in one document, when appropriate, and upload separately on IRBNet. PDFs of online surveys may be uploaded in a second document, as needed.

2) List all Data Collection materials. Data Collection materials include but are not limited to surveys, handouts, demographic forms, assessment tools, and interview questions.

- ☒ Assessment Tools
- ☐ Demographic Forms
- ☐ Interview Questions
- ☐ Handouts
- ☐ Online Survey:

  Please provide the survey's URL:

  Please also provide a PDF of the survey as a separate upload.
- ☐ Surveys (paper) - Please upload as a separate document.
- ☐ Other (if other, please list all other forms of data collection below)

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Proposal to Conduct Human Subjects Research

Study Title

Ocular Adaptation and Visual Performance for Accommodative Contact Lens

Research Personnel

Investigator(s)
Shun-Nan Yang, Susan Resnick, Patrick Caroline, David Geffen and Timothy Poling

Faculty Investigator (required for student investigator research)

Clinical Investigation

Clinical Investigation ■ **YES** ☐ **NO**

Please provide all Clinical Investigation Information on the *IRB Proposal Guidance Document*.

Purpose

Provide enough relevant information to allow the IRB reviewers to understand the rationale and/or justification for the study and its merits (basic and/or applied), including any relevant study hypotheses and dissemination plans.

Presbyopia is an ocular condition resulting from the reduced flexibility and consequent loss of accommodation, an ability to change the optical power of the human crystalline lens. It results in a limited range of focal distances for forming a clear retinal image. The typical clinical solution to presbyopia is the fitting of single-vision or multifocal spectacle lenses. Alternatively, single- and multi-focal contact lens can be fitted for presbyopes who can adapt to contact lens wearing. Multi-focal lenses provide the convenience of changing focal distances with a single lens; however, unwanted aberrations due to transition between optical zones for different focal distances can be a significant compromise with these solutions.

OneFocus Vision, Inc. (OFV) has previously bench-tested a proprietary design of accommodative contact lens (ACL), and would like to contract the Vision Performance Institute for a non-dispensing (within-laboratory wearing only) clinical test. This novel design of ACL is based on the interaction between the force exerted by the lower eyelid and the fluid (saline or contact lens solution) inside a cavity within the contact lens. The cavity exists within the lens between two layers of hydrogel, and does not get in touch with the corneal surface. The water-absorbing/peameating hydrogel also allows the cavity to be filled with fluid. When the lens is stored in saline or in lens care solution, the cavity will be fillled with saline or lens care solution respectively. When it is taken out of the storage box and worn over the eye during the testing, the saline or lens care solution should mostly remain in the cavity, and some (if any) tears might be absorbed into the cavity. OFV bench tests have shown that when micro-pressure (from the lower lid) is applied to the surface above the reservoir(s) containing the fluid, the fluid is pushed through channel(s) and enters a large reservoir extending throughout the optical zone that covers the pupil. Such action in turn changes the optical power of the contact lens that covers the pupil of the eye.

OFV would like the Vision Performance Institute (VPI) at Pacific University and the additional sites (hereafter referred to as Salen, San Diego and New York sites or collectively as the "Co-investigational sites") to conduct testing to confirm the functionality of the test lens on voluntary participants, and to measure the visual performance afforded by the test lens. The three sites will hold their own contract with OFV, but that all data will be processed and published through the VPI.

In the proposed non-significant risk study we plan to recruit presbyopes (people who might have a significant loss of their ability to accommodate their crystalline lens in the eye) to wear a test lens and perform typical clinical tests of visual acuity with different luminance levels and viewing distances/angles. FDA approved commercial ophthalmic equipment will be used at these sites to take images of the test lens on the cornea. These are similar to the typical examinations conducted for regular contact lens wearers. Results of this testing will be used to evaluate the efficacy of test lenses and to provide additional information for revision of test lenses. If shown to provide adequate eye comfort and intended vision correction, this lens design has the potential of allowing tens of millions of presbyopes to utilize contact lenses to improve their functional, everyday vision.

Recruitment

1. Describe the Sample Size and relevant demographics.

Sixty four participants will be enrolled into the study. Up to 110 potential participants will be recruited at the four sites and screened to obtain the needed sample size of 64. Participants should be between 40 and 75 years of age. The number of 64 subjects will allow for detection of a .5 Standard Deviation difference in response time and accuracy with 80% statistical power. This number of participant is usually required for a stage 2 clinical study for validating the efficacy of device design. They will be recruited through flyers posted online (websites) and on bulletin boards around the community surrounding the Forest Grove Campus of Pacific University and other associated eye clinics (see included Flyers).

2. Describe and justify the inclusion of any non-autonomous subjects. ■ N/A

3. Eligibility Criteria?

List and describe the key characteristics necessary for participants in the study.

- Be between 40 and 75 years of age.
- Have normal/corrected-to-normal monocular acuity of better than 20/25 for both eyes.
- Have a photopic (with light stimulation) pupil diameter ≥ 2.5 mm.
- Willing and able to wear multifocal contact lenses in both eyes.
- Have a current optical prescription (obtained less than 2 years ago).
- Have spherical equivalent correction equal to or higher than -1.00 Diopter and equal to or less than +0.50 Diopter.
- Have cylindrical correction equal to less than 0.50 Diopter.

4. Exclusionary Criteria

List and describe the criteria that would exclude subject participation in the study (e.g., pregnancy, specific medical condition, English language fluency, age, etc.).

- Have no prismatic correction.
- Without any eye infection, inflammation, disease, or abnormality that contraindicates contact lens wear within the past 6 months.
- No clinically significant ocular pathology (e.g., cataract, keratoconus, dry eye, diabetic retinopathy, or age-related macular degeneration)
- Have no photosensitive disorders, including migraine and seizure.
- Have no binocular dysfunction, including amblyopia, strabismus, and other binocular diseases.

5. Recruitment Plan

Participants will be recruited from the general population using separate recruiting flyers for the four sites (see Recruiting Flyers). The flyers will be posted on the bulletin boards at affiliated eye clinics and other public places, including community centers, local restaurants, and coffee shops. Research personnel will request to post flyers from the appropriate individuals at each location. Participants will call one of the four sites nearest to them, as noted on the flyer, to express their interest in the study and inquire about study criteria. An optometrist (Drs. Patrick Caroline at VPI, Timothy Poling in Salem, David Geffen in San Diego, or Susan Resnick in New York) will speak

with the potential participants on the phone to explain the study criteria and to determine if they meet the criteria included on the recruitment flyer. Candidates satisfying the screening criteria will be invited to the first vision exam session and the exam will be scheduled.

At the beginning of the vision exam session, the subject's consent to the study will be obtained first by the optometrist. S/he will then be examined by the optometrist based on the inclusion and exclusion criteria and tested with their habitually-worn spectacle lenses or contact lenses, if any. Those satisfying the criteria will then be formally entered into the second phase of study.

Study Methodology

1. Location of the Study

Four sites will be involved in the study:

1. VPI: The study will be conducted in Room 234 of Jefferson Hall at the Forest Grove campus. Dr. Caroline will conduct the vision screening and lens testing.
2. Salem clinic: Testing will be conducted at 511 Roanoke Blvd Suite 1, Salem, VA 24153. Dr. Poling will conduct the vision screening and lens testing.
3. San Diego clinic: Testing will be conducted at 8910 University Center Lane Suite 800, San Diego, CA 92122. Dr. Geffen will conduct vision screening and lens testing.
4. New York clinic: Testing will be conducted at 30 East 60th Street, New York, NY 10022. Dr. Resnick will conduct the vision screening and lens testing.

2. Study Materials, Measures, and/or Apparatus to be Applied

• Test lens: Contact lenses manufactured with standard soft contact lens material, hydrogel, will be tested (see Technical Description of Test Lens). Based on the FDA procedure for classifying medical devices, the test lens should have an expected rating as a Class II, 510K device: proposed identifier 886.5925; product code, LPL (see FDA Device Regulation Guidance at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm). The test lens' biological compatibility also meets the FDA testing guidance, as demonstrated by the provided ocular irritation and toxicity reports for soft contact lens (see Ocular Irritation and Toxicity Reports)
• Video image of test lens: Infra-red video camera will be used to record the position of test lens in relation to the edge of pupil and lower eyelid.
• Corneal and test lens profile Image: Ocular coherence topography (OCT) will be taken with Zeiss Cirrus OCT (VPI) or similar anterior segment OCT (Co-investigational sites). Corneal and lens topography will be taken with the Medmont Topography System (VPI) or similar corneal topographer (Co-investigational sites) The OCT and topographer data will be used to visualize the position and shape of the test lens relative to the corneal surface.
• Measure of lens refraction power: Shin Nippon SRW-5500 Open Field Autorefractor (VPI) or other clinical autorefractor (Co-investigational sites) will be used to measure the refractive power and pupil size at different distances and downward angles with and without the test lens.
• Visual acuity testing: An M&S visual acuity testing system (VPI) or similar computerized visual acuity testing system (Co-investigational sites) will be used to display high (95%) and low-contrast (10%) Snellen letters at distance (6 meters), intermediate (75 cm) and near (40 cm) testing distances.

3. Procedures

• Telephone Interview

Each participant will first talk to the optometrist who will determine whether they meet the recruiting criteria. If they meet the criteria, an appointment for the vision exam session will be scheduled.

• Visions Exam Session

During the vision exam session, they will first read, question and sign the consent form. They are now formally enrolled in the study and will then be examined by an optometrist (Drs. Caroline, Poling, Geffen or Resnick). Distant monocular acuity, distance phoria, and accommodative amplitude will be measured. Additional refractive examinations will be conducted to ensure his/her eligibility. The participant will also be screened for any ocular diseases listed in the exclusion criteria. This will take about 45 to 60 minutes. Participants meeting the screening criteria will be invited back for the lens testing session. The second testing session can be scheduled immediately after the vision exam session or on a subsequent date, if it is more convenient for the patient. In the event that the participant chooses to return on a subsequent date, the optometrist will verbally re-consent the participant before the session begins.

• Testing

The formal testing session will last about 2 hours. At the beginning of the session, corneal topography will be taken without the test lens. The participant will then put on the test lens and corneal topography and corneal ocular coherence topography (OCT) will be taken while s/he views with 0, 15, and 25 degrees of downward angle. The viewing angle is enforced with a forehead/chin rest.

In the second task, participants will be asked to view an eye chart with the 3 downward angles (0, 15, and 25 degrees) and 6m, 75cm, and 40cm distances while their optical refraction is measured with a power refractor. The measured results are then compared to the accommodative demand at these 3 distances.

In the third task, eye charts will be presented at the 3 distances and corresponding angles (6 m for 0 degree, 75 cm for 15 degree, 40 cm for 25 degree)

In the fourth task, video images of the ocular surface will be taken while the eye shifts between 0 to 15 and 25 degrees downward angles and during eye blinks. An infra-red video camera will be mounted on a post in front of the measured eye to acquire the eye images at 15 Hz. These are done for both eyes.

At the completion of the fourth task, the test lens will be removed from participant's eyes. A slit lamp exam will be conducted to at the beginning and end of contact lens wearing to ensure there is no damage to the cornea. The test lens will also be inspected to confirm its integrity. An exit survey will then be conducted and documented to ensure there is no unexpected effect or symptoms except those typically observed with the wearing of soft contact lens (see List of Information Shared with the Sponsor). All data will be aggregated at VPI and then shared with the sponsor based on the above list of shared information.

4. Timeline for Recruitment, Data Collection, Analysis, and Dissemination

Recruiting will begin once IRB approval has been obtained. Data collection will begin immediately after IRB approval and continue until December 31, 2018. Data analysis will be completed before September 30, 2019. Findings will be submitted for publication at an optometric conference once data analysis is completed.

After the completion of data collection, a summary of test results and samples of photos and video images will be provided to the sponsor (see List of Information Shared with the Sponsor). Data collected from the three other sites will be sent to Pacific University who will then share them with the sponsor. The summary report will not include any individual data. All individual images and video/photos will be prepared in a way so that they cannot be used to identify the participant from whom they are taken.

Risks

1. Specifically identify and briefly describe the various risks to which participants may be exposed.

Regarding study risk determination, this study is proposed as a non-significant risk study. Safety testing in accordance with FDA testing requirements for a daily wear contact lens indicates the hydrogel material has been deemed as safe for use in human subjects when the lens is to be exposed to patients for daily use. The study is intended as a non-dispensing, feasibility study to evaluate the design of the accommodating contact lens and poses minimal risk to subjects under the conditions of the study.

Possible risks during testing include a minimal level of eye symptoms similar to what the participant would experience in wearing contact lenses. The symptoms include dry eye and general discomfort but will be short term in nature – probably not extending beyond the testing

session. There is minimal risk in exposing the participant to 2 hours of testing.

2. Describe the likelihood of these risks occurring, how they can and will be minimized, and how they will be handled should they occur.

Viewing discomfort can occur due to dry eye and wearing discomfort. Breaks will be scheduled after each of the four tasks to keep these symptoms at a minimal level. If the discomfort reaches a level that interferes with task performance (as reported by the participant), the task will be paused and the test lens taken out. This should allow the symptoms to dissipate. The participant can terminate their participation or is allowed to resume the task only after the symptoms dissipate to a level that is acceptable to the participant and does not interfere with further participation.

Slit lamp examination will be conducted to confirm the health of the eyes after contact lens wear.

3. Describe any element(s) of deception of meaningful withholding of information associated with the study methodology.

There will be no deception or information withholding involved in the study.

4. Describe any treatment alternatives that may be advantageous to subjects, if clinical investigations are involved.

Alternative treatments available to participants include wearing bi-focal or multi-focal spectacle glasses or contact lenses, or not participating in the study.

Adverse Events

How will adverse events be handled and reported?

Development of any unusual or acute eye discomfort should be relieved immediately by pausing the experiment and taking out the test lens. Although none are expected, any unusually severe and long lasting eye discomfort, that cannot be mitigated by pausing the testing, will be noted and reported to the Institutional Review Board on the next business day. Appropriate modification of the testing procedure will be made to reduce such issues and submitted to the IRB before testing of the lenses continues.

Benefit or Compensation

1. Describe the specific unique benefits subjects will realize via their participation in this study, if any.

We expect no direct benefit to the participants.

2. Describe the payment or other reward participants will receive, if any.

All consented participants will be compensated $50 for the 1-hour vision exam session, and additional $100 for the 2 hours of lens testing session. They will receive $50 if they participate in the vision exam session, but are not invited back for the lens testing session. They will need to provide their Social Security number to receive the payment. If they are a Pacific University employee, their payment will be reported to Payroll (depending on the value of the award/prize, it may be taxable).

For those participating at the VPI site, they will be required to complete the Research Participant Payment Form prior to receiving payment for participation. Additional Pacific University policies regarding payment are included on that form. This form is provided for at the end of the consent documentation as a reference for participants. For those participating at the Salem, San Diego and New York sites, the same form and policy documents will also be provided.

Privacy

How will you protect the privacy of your participants?

All recorded images, examination records, and behavioral performance results will be numerically coded and kept in a file cabinet within a room that is always locked when the research personnel is not in it. Only the PI will have access to the file cabinet. Consent forms will be kept separately from study data. All documents collected from the Salem, San Diego and New York sites will be sent to the VPI and stored separated from study data.

Summary report with group data and de-identified images and videos will be provided to the sponsor for the evaluation of test lens.

Confidentiality will be further preserved by coding individual results with numbers and only mean or group data will be presented in the publication of the results. Any images from the study will be rendered in a way so that the participant cannot be identified. Through use of code numbers, the subjects' identities will be shielded from subsequent testing and data report. Study data and consent forms will be maintained securely for three years after the completion of the study or the date of publication on a journal. After the deadline, the date and document will be destroyed.

Informed Consent

1. How will informed consent be obtained and documented?

Describe the consent process for your study.

After the participant is determined to meet the recruiting criteria based on the phone interview, s/he will be invited to participate in the vision exam session. At the beginning of the vision exam session, a brief description of the vision exam procedure and an explanation of the experimental setup for the lens testing session will be given to the participant by an optometrist (Drs. Zheng, Poling, Geffen or Resnick) using terms appropriate for them to understand. They are encouraged to ask any questions they might have about the study.

The participant will then read, question, and sign the consent form approved by the Institutional Review Board at Pacific University. If the subject agrees to participate, s/he will be given a copy of the consent form for their record.

If results of the vision exam meet all criteria, the participant will be invited to participate in the second (lens testing) session. If the results do not meet the criteria, his/her participation will be terminated and s/he will be compensated for the first hour of participation. An explanation will be given to the participant as why her participation is terminated, and documented on the consent form.

2. How will participant assent be obtained and documented?

Not applicable.

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Medical Device Study Information

Study Title

Ocular Adaptation and Visual Performance for Accommodative Contact Lens

Research Personnel

Investigator(s)
Shun-nan Yang, Patrick Caroline, Timothy Poling, Susan Resnick and David Geffen

Faculty Investigator (required for student investigator research)

Medical Device Information

This form is to be used if a medical device, or multiple medical devices, is the subject of study in this protocol. If medical devices are being used for their intended and approved purposes and are not the subject of study, please modify your response to the Medical Device Question.

1. Clearance and/or Approval and Use Information

Medical Device #1
Medical Device Name **Accommodative contact lens**
PMA Numbers(s) (as applicable) Not applicable
501(k) Numbers(s) (as applicable) Not applicable
Additional Information, as needed

Check all that apply. Please attach the product label information, if available, as a separate document on IRBNet (entitled "Product Name" - Label Information).

- ☐ This study involves research on a **medical device** that is cleared and/or approved for marketing.
- ☐ The **medical device** is being used in accordance with its approved indications, with no modifications (on-label use).
- ☐ The **medical device** is **not** being used in accordance with its approved indications (off-label use).
- ■ This study involves research on a **medical device** that has **not** been cleared and/or approved for marketing.

2. Investigation Device Exemption (IDE)

Check all that apply.

☐ This study involves an investigation that is **exempt** from the **IDE** requirements (21 CFR 812.2(c)).

☐ This study involves an investigation for which an **IDE <u>is</u>** required.

- ☐ **IDE** approval has been obtained from the FDA (please submit as separate document).
- ☐ **IDE** approval has **<u>not</u>** been obtained from the FDA.
- ☑ **IDE** approval is automatic because the study is determined to be non-significant risk.

3. Significant Risk (SR) or Non-Significant Risk (NSR) Determination

Check all that apply.

☐ This is a **SR** medical device (21 CFR 812.3(m)) study.

☑ This is a **NSR** medical device study.

- ☐ **A NSR** determination has been obtained from the FDA (please submit as separate document).
- ☑ **A NSR** determination has **<u>not</u>** been obtained from the FDA.

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Informed Consent

Study Title

Ocular Adaptation and Visual Performance for Accommodative Contact Lens

Research Personnel and Contact Information

Personnel #1	
Name **Shun-nan Yang**	**Role** Principal Investigator
Institution Pacific University	**Program** College of Optometry
Email shunnan.yang@pacificu.edu	**Telephone** (503)352-2852
Scope ☐ Recruitment ☐ Consent Process ☐ Data Collection ■ Data Analysis (with personally identifiable information) ■ Data Analysis (de-identified data) ☐ Other: _____	

Personnel #2	
Name **Site Optometrist**	**Role** Co-Investigator
Institution Office Name	**Program**
Email corresponding email	**Telephone** site number
Scope ■ Recruitment ■ Consent Process ■ Data Collection ■ Data Analysis (with personally identifiable information) ■ Data Analysis (de-identified data) ☐ Other: _____	

Study Invitation | Purpose | Location | Dates

You are invited to participate in a study about a specially designed contact lens. The lens can help people with presbyopia see both near and far objects. You are invited because the lens is mostly likely to help people around your age (40 to 65 years old) see more clearly at different viewing distances. This consent form informs you about the study so you can decide if you should be in the study or not.

The study involves two sessions at [Specific Site] Office. In the first session, a 40- to 60-minute vision exam will be conducted by an optometrist to determine if you can participate in the second session. If results of the vision exam indicate that you meet all criteria, you

will be invited to participate in the second session. You can begin the second session immediately after the vision exam session, or schedule it on a later date. We will ask you to confirm your agreement to participate at the beginning of the second session if it is scheduled on a later date. In the second session you will view simple eye charts while wearing the special contact lens. The testing will last about two hours. You can take breaks during testing when you need it. We will use several machines to take images of your eyes to evaluate how well the lens fits your eyes. You will be using a chin/forehead rest to keep your head still while we take these pictures. You can withdraw from this study at any time.

This study has been approved by the Institutional Review Board of Pacific University. It will take place from January 2018 to December 31, 2018 at [Specific Site Address]. Although results of this study do not directly benefit you, we might find out information that will help improve the design of contact lens for people around your age.

You can ask me, [Site Co-investigator], any questions about this study now. I can answer questions related to the study for you. You also can talk to the principle investigator (PI), Dr. Shun-nan Yang, about this study. His phone number is 503-352-2852. After all your questions have been answered, you can decide if you would like to be in this study or not.

Participant Characteristics and Exclusionary Criteria

You are qualified to participate in the study if you can satisfy the following requirements:
- Be between 40 and 75 years of age.
- Have normal/corrected-to-normal monocular acuity of better than 20/25 for both eyes.
- Have a pupil diameter ≥ 2.5 mm under room light.
- Willing and able to wear multifocal contact lenses in both eyes.
- Have a current optical prescription (obtained less than 2 years ago).
- Have spherical equivalent correction equal to or higher than -1.00 Diopter and equal to or less than +0.50 Diopter.
- Have cylindrical correction equal to less than 0.50 Diopter.

You cannot participate in the study if you have any of the following conditions:
- Have prismatic correction.
- Have any eye infection, inflammation, disease, or abnormality that prevents contact lens wear within the past 6 months.
- Have clinically significant ocular pathology (e.g., cataract, keratoconus, dry eye, diabetic retinopathy, or age-related macular degeneration)
- Have photosensitive disorders, including migraine and seizure.
- Have binocular dysfunction, including amblyopia (lazy eyes), strabismus, and other binocular diseases.

Study Materials and Procedures

In the proposed study we plan to recruit and test up to 110 people who are between 40 and 65 years of age and likely have significantly loss in their ability to accommodate their crystalline lens in the eyes. Participants in this study will wear specially designed contact lenses and perform typical clinical tests of visual acuity with different luminance levels and viewing distances/angles. These are similar to the typical examinations conducted for regular contact lens wearers. The duration of eye exam and testing are about 3 hours. Results of this testing will be used to evaluate the efficacy of the test lens and to provide additional information for improving its design. If shown to provide adequate eye comfort and intended vision correction, this lens design has the potential of allowing tens of millions of presbyopes to utilize contact lenses to improve their functional, everyday vision.

Risks | Risk Reduction Steps | Clinical Alternatives

1. Anticipated Risks and Strategies to Minimize or Avoid Risk

Possible risks during testing include a minimal level of eye symptoms similar to what you would experience in wearing soft contact lenses. The symptoms include dry eye and general discomfort but will be short term in nature – probably not extending beyond the testing session. There is minimal risk in exposing the participant to 2 hours of testing.

In addition, this experimental contact lens has not been approved or presented to the FDA for approval, as it is still in the development

phase. The sponsor, OneFocus Vision (8358 Sanctuary Lane, Fernandina Beach, FL 32034; Phone number 404-405-0109) has made reasonable efforts to test biologically active elements and have found no evidence that they would cause infection or irritation. Additionally, the investigator and sponsor agree that this lens is biologically similar to other products on the market. However, you as a participant need to know that this device is not currently regulated by the FDA, although it may be in the future. If you would like to have laboratory results documenting the safety of the lens, we can provide them to you.

2. Unknown Risks

It is possible that participation in this study may expose you to currently unforeseeable risks.

3. Advantageous Clinical Alternatives

The specially designed contact lens is an experimental design but made of the same material as currently commercially available contact lens (hydrogel). Currently the alternative to wearing this kind of special lens is to wear eye glasses or contact lens with single- or multi-focal distances.

Adverse Event Handling and Reporting Plan

In the event that you become sick, injured, distressed, or otherwise uncomfortable as a result of your involvement in the research study, you may stop your participation immediately. If such an event occurs, promptly notify the principal investigator or the Pacific University Institutional Review Board.

If the investigator(s) become aware of an adverse event, the IRB office will be notified by the next normal business day for any minor events, such as persistent visual or physical discomfort you might experience, and within 24 hours for major events such as severe physical illness.

If you experience or are directly affected by an adverse event, you will be given the opportunity to withdraw any data collected from you during the study up to the point of the publication of the study results.

Direct Benefits and/or Payment to Participants

a. Benefit(s)

We expect no direct benefits to you. Depending on the findings, benefits may accrue to the general population of contact lens wearers from which this sample is drawn.

b. Payment(s) or Reward(s)

You will be compensated for $50 for the 1-hour vision exam, and additional $100 for the 2-hour of lens wearing and testing). You will only receive $50 if you participate in the vision exam session but are not invited back for the second lens testing session. You will need to provide personally identifiable information in order to receive the payment. If you are a Pacific University employee, you payment will be reported to Payroll (depending on the value of the award/prize, it may be taxable).

Promise of Privacy

All recorded images, examination records, and testing results will be identified by only numbers and kept in a locked file cabinet. Only the PI will have access to the file cabinet. Consent forms will be kept separately from study data. Results from your testing will be reported as grouped data. Any images or videos from the study will be prepared in a way so that you cannot be identified, even by the PI. Through use of code numbers, your identity will be shielded from subsequent data report. Study data and consent forms will be maintained securely for three years after the completion of the study or the date of publication on a journal. After the deadline, the date and document will be destroyed.

A description of this clinical investigation will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

As part of ongoing compliance efforts, the Food and Drug Administration (FDA) may inspect any and all records pertaining to this study. FDA auditors maintain strict confidentiality of all records reviewed.

In addition, efforts will be made to limit use or disclosure of your personal information to persons approved as study staff. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB of Pacific University, and representatives responsible for the management or oversight of this study. The sponsor will have limited access to data, whereas monitors, auditors, the IRB, and the FDA will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Medical Care and Compensation in the Event of Accidental Injury

☐ **N/A**

During your participation in this project it is important to understand that you are not a patient or client of Pacific University clinic or other investigative clinic sites, nor will you be receiving complete eye care as a result of your participation in this study. If you are injured during your participation in this study and it is not due to negligence by Pacific University, the investigator(s), or any organization associated with the research, you should not expect to receive compensation or medical care from Pacific University, the investigator(s), or any organization associated with the study. If you are injured and it directly is related to your participation in this study as a research subject, please contact the Pacific University Institutional Review Board at 503-352-1478.

Voluntary Nature of the Study

Your decision whether or not to participate will not affect your current or future relations with Pacific University and associated testing clinics. If you decide to participate, you are free to not answer any question or withdraw at any time up until the study data is published without prejudice or negative consequences. If you choose to withdraw after beginning the study but prior to publication, you will be compensated for the time you have spent and the data collected from you will be destroyed. If significant new findings develop (or are discovered) during the course of this research that could impact your decision to continue participation, such findings will be shared with you and you will be given the opportunity to withdraw from the study.

Contacts and Questions

The investigator(s) will be happy to answer any questions you may have at any time during the course of the study. If you are not satisfied with the answers you receive, please call the Pacific University Institutional Review Board at 503-352-1478 to discuss your questions or concerns further. If you have questions about your rights as a research subject, or if you experience a research-related injury of any kind, please contact the investigator(s) and/or the IRB office. All concerns and questions will be kept in confidence.

Statement of Consent

YES NO

____ ____ I am 18 years of age or over.

____ ____ All my questions have been answered.

____ ____ I have read and understand the description of my participation duties.

____ ____ I have been offered a copy of this form to keep for my records.

____ ____ I voluntarily agree to participate in this study and understand that I may withdraw at any time without consequence.

Signature	Date
Printed Full Name	Participant Study Role
Signature	Date
Printed Full Name	Study Role*

*This individual must be trained in obtaining informed consent and have authorization from the principal investigator and/or faculty advisor to do so.