

Pacific University

CommonKnowledge

---

College of Optometry

Theses, Dissertations and Capstone Projects

---

5-2003

## Development of informed consent forms for three contact lens fitting modes

Adam Dayley  
*Pacific University*

Brian McCollom  
*Pacific University*

### Recommended Citation

Dayley, Adam and McCollom, Brian, "Development of informed consent forms for three contact lens fitting modes" (2003). *College of Optometry*. 1431.  
<https://commons.pacificu.edu/opt/1431>

This Thesis is brought to you for free and open access by the Theses, Dissertations and Capstone Projects at CommonKnowledge. It has been accepted for inclusion in College of Optometry by an authorized administrator of CommonKnowledge. For more information, please contact [CommonKnowledge@pacificu.edu](mailto:CommonKnowledge@pacificu.edu).

---

## Development of informed consent forms for three contact lens fitting modes

### Abstract

Contact lens materials and fitting techniques are evolving rapidly, and with this evolution comes new potentially unforeseen problems. The clinics are in need of contemporary consent forms in order to protect Pacific University and its students from potential lawsuits. The forms would also serve as a useful education tool for each patient prior to the fitting and dispensing of contact lenses. Therefore, our project will serve not only as a legal protective mechanism, but will also serve as an important educational tool for both the patient and intern regarding the potential risks associated with contact lens use.

### Degree Type

Thesis

### Degree Name

Master of Science in Vision Science

### Committee Chair

Peter Bergenske

### Subject Categories

Optometry

## Copyright and terms of use

If you have downloaded this document directly from the web or from CommonKnowledge, see the "Rights" section on the previous page for the terms of use.

**If you have received this document through an interlibrary loan/document delivery service, the following terms of use apply:**

Copyright in this work is held by the author(s). You may download or print any portion of this document for personal use only, or for any use that is allowed by fair use (Title 17, §107 U.S.C.). Except for personal or fair use, you or your borrowing library may not reproduce, remix, republish, post, transmit, or distribute this document, or any portion thereof, without the permission of the copyright owner. [Note: If this document is licensed under a Creative Commons license (see "Rights" on the previous page) which allows broader usage rights, your use is governed by the terms of that license.]

Inquiries regarding further use of these materials should be addressed to: CommonKnowledge Rights, Pacific University Library, 2043 College Way, Forest Grove, OR 97116, (503) 352-7209. Email inquiries may be directed to: [copyright@pacificu.edu](mailto:copyright@pacificu.edu)

DEVELOPMENT OF INFORMED CONSENT FORMS  
FOR THREE CONTACT LENS FITTING MODES

By

Adam Dayley, BS

Brian McCollom, BS

A thesis submitted to the faculty of the  
College of Optometry  
Pacific University  
Forest Grove, Oregon  
For the degree of  
Doctor of Optometry  
May 2003

Advisors:  
Peter Bergenske, OD  
Jennifer Smythe, OD

SIGNATURE PAGE

AUTHORS:

ADAM DAYLEY

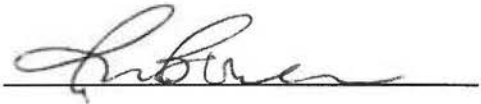
A handwritten signature in cursive script, appearing to read 'Adam Dayley', written over a horizontal line.

BRIAN MCCOLLOM

A handwritten signature in cursive script, appearing to read 'B McCollom', written over a horizontal line.

ADVISORS:

PETER BERGENSKE

A handwritten signature in cursive script, appearing to read 'Peter Bergenske', written over a horizontal line.

JENNIFER SMYTHE

A handwritten signature in cursive script, appearing to read 'Jennifer Smythe', written over a horizontal line.

## **ABSTRACT**

Contact lens materials and fitting techniques are evolving rapidly, and with this evolution comes new potentially unforeseen problems. The clinics are in need of contemporary consent forms in order to protect Pacific University and its students from potential lawsuits. The forms would also serve as a useful education tool for each patient prior to the fitting and dispensing of contact lenses. Therefore, our project will serve not only as a legal protective mechanism, but will also serve as an important educational tool for both the patient and intern regarding the potential risks associated with contact lens use.

## **ACKNOWLEDGEMENTS**

The authors would like to express our appreciation to all those who assisted in completion of our thesis. We would like to thank our advisors, Dr. Peter Bergenske and Dr. Jennifer Smythe for their guidance and assistance in the completion of the forms. A very special thanks to our fellow Colleges of Optometry who took the time to send us forms currently utilized at their facilities.

Today the profession of optometry is in a dynamic state of change. The role of optometry in the United States has expanded to include procedures and treatment methods which carry increased risks and liability. It is important as optometric physicians to accurately and completely inform our patients of the inherent risks and possible complications of some procedures. Today the use of an informed consent form serves to both educate the patient as well as to minimize liability of the optometrist.

Informed consent has evolved primarily from legal cases in which injured patients have claimed that their physician had failed to adequately address the risks associated with a given treatment (1). Early medicine, as reflected in the Hippocratic writings, indicated that a physician's judgement and treatment method were not questioned by the patient. Patients at this time were usually not advised as to the risks and complications of their procedure. This attitude changed in 1914 when Justice Cardozo stated, "...every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages" (2). Today lack of proper patient consent is considered medical negligence instead of an assault.

Informed consent has arisen from the patient's right to be reasonably informed and involved in the decision-making process involving his/her health care. Informed consent is inferred that both the physician and the patient are active participants in their care. In this model, the doctor and the patient are "partners" in care (3).

As the role of today's optometrist has expanded, the use of informed consent forms has become more important. Informed consent should be considered prior to pupillary dilation, initiating therapeutic treatment involving the prolonged use of



corticosteroids, and in the management of complex ocular disease conditions including glaucoma. Consent forms are also needed prior to performing medical research.

Another very important area of informed consent is that of contact lens use and maintenance. Patients must be adequately informed as to possible ocular complications which may arise from the use of the various lens modalities. Proper use of the informed consent form also “prepares the patient for his or her responsibilities as a contact lens wearer by emphasizing that the patient is entering into a comprehensive treatment plan, one that requires long-term compliance” (4). These forms also help the clinician provide adequate information to their patients which will assist in patient understanding of the fitting procedure and enhance patient compliance involving contact lens care and follow-up appointments (5). Proper patient communication and consent serves to greatly minimize legal proceedings against the practitioner in the event of future patient dissatisfaction. By making the patient aware of possible complications prior to their surfacing, the patient will feel less obligated to seek claims in a court of law, providing that the patient understands that joint responsibility is critical to the success of contact lens use (6).

In developing an informed consent document, there are certain aspects which must be covered in order for the form to serve its intended purpose. The element most heavily emphasized is that of disclosed risks. The form should include the risks, described in lay terms, that a reasonable person would wish and need to know (7). The form should also include information regarding the signs and symptoms of contact lens complications, as well as the outlined procedures to follow in the event such complications occur.

The consent form should also make very clear that the patient bears responsibility in the proper care and utilization of the lenses. It should be stated clearly that failure to adhere to the instructions outlined by the doctor including proper lens care and maintenance may result in undesirable complications, or cessation of the contact lens program. In addition, the patient must be willing to be present at all scheduled follow-up appointments as outlined by the doctor.

An informed consent form must also include alternative methods to the proposed therapy. The patient should be informed of all methods, including those that carry increased risks such as current refractive surgery procedures. It is particularly important in the case of extended wear to inform the patient of alternative therapies including daily wear lenses or spectacles, as these methods are generally considered to represent safer modalities of refractive error correction. In each case, the pros and cons of each procedure should be discussed with the patient.

The concluding portion of the informed consent form should include an offer to answer any of the patient's questions regarding the treatment procedure (8). Once the patient is comfortable that all questions have been satisfactorily answered, and that all of their responsibilities have been made clear, the patient will sign and date the form. In the event the patient is a minor, a parent or guardian will consent for the minor.

It is advisable that the informed consent be carbon copy forms. The patient is given the copy and the doctor retains the original in the patient's file (9). In the event of a legal dispute, a patient has very little chance of winning if they have signed and dated a proper informed consent form. For this reason, it is very important to maintain the signed originals safely in the patient's record.

## Conclusion

Informed consent forms represent a practical means of both educating patients and minimizing legal action against today's practitioner. As the scope of optometry has expanded, today's optometrist faces greater liability for their actions. By comprehensively educating our patients regarding risks associated with certain procedures, and effectively communicating the role of the patient in the process, future disagreements can be minimized before such legal actions are taken. The effective sharing of information can enhance the doctor-patient relationship, and elevate the status of optometry in the public's image.

## BIBLIOGRAPHY

1. Appelbaum, Paul S., Charels W. Lidz, and Alan Meisel. *Informed Consent Legal Theory and Clinical Practice*. New York: Oxford University Press, 1987: 35-65.
2. Finkelstein, Daniel, Melanie Karsh Smith, Ruth Faden. "Informed Consent and Medical Ethics." *Arch Ophthalmos* Vol 111 March 1993: 324-326.
3. Annas, George J. *The Rights of Patients*. Carbondale: Southern Illinois University Press, 1989: 34-47.
4. Classe, John G. *Legal Aspects of Optometry*. Boston: Butterworth –Heinemann, 1989: 373-396.
5. Classe, John G. *Legal Aspects of Optometry*. Boston: Butterworth –Heinemann, 1989: 373-396.
6. Annas, George J. *The Rights of Patients*. Carbondale: Southern Illinois University Press, 1989: 83-103.
7. Finkelstein, Daniel, Melanie Karsh Smith, Ruth Faden. "Informed Consent and Medical Ethics." *Arch Ophthalmos* Vol 111 March 1993: 324-326.
8. Miller, Pamela J. "Clinico-Legal Aspects of Infantile Strabismus." *Optometry and Vision Science* Vol 67 No. 2 1990: 148-149.
9. Classe, John G. *Legal Aspects of Optometry*. Boston: Butterworth –Heinemann, 1989: 373-396.

# **APPENDIX**

Informed Consent for Daily Contact Lens Wear

Informed Consent for Continuous Wear (Overnight) Contact Lenses

Informed Consent for Orthokeratology



Forest Grove Clinic
(503) 357-5800

Downtown Portland Clinic
(503) 224-2323

Informed Consent for Daily Contact Lens Wear

Welcome to Pacific University's College of Optometry Family Vision Center!!

Contact lenses represent an exciting means for the correction of refractive error. A thorough ocular examination assessing eye health, eyeglass prescription, and your suitability for contact lens wear must be performed prior to dispensing of contact lenses.

IN THE BEGINNING IT IS NORMAL IF YOU EXPERIENCE THE FOLLOWING:

- YOUR EYES ITCH OR FEEL FUNNY WHILE WEARING THE LENSES.
ONE LENS IS MORE NOTICEABLE THAN THE OTHER.
YOUR VISION SEEMS FUZZIER THAN GLASSES.
ONE EYE SEES BETTER THAN THE OTHER.
YOU HAVE TROUBLE HANDLING YOUR LENSES.

REMOVE YOUR LENSES IMMEDIATELY IF YOU EXPERIENCE ANY OF THE FOLLOWING:

- UNUSUAL EYE PAIN
EXTREME SENSITIVITY TO LIGHT
EXTREME REDNESS OF THE EYE
DAMAGE TO A LENS
EXCESSIVE TEARING OR EXCESSIVE DRYNESS
PROLONGED BLURRY OR UNCLEAR VISION
UNUSUAL CLOUDY OR FOGGY VISION
YOU SUSPECT SOMETHING IS WRONG

Contact Lens Care
Proper care is necessary for successful wear, normal lens life, and good eye health. You will be provided with products with which you will clean, disinfect, and store your lenses.
Care System
Re-wetting
Replace Lenses

Discontinuing lens wear after experiencing these symptoms should provide relief. If these symptoms persist after lens removal, you should immediately call for an appointment or consultation with your eye care practitioner who will provide the necessary treatment.

BY SIGNING BELOW I AGREE THAT:

I understand that I am being fit with daily wear contact lenses and that my cooperation and compliance is vital to the success of their use. I understand that my lenses are designed solely for daily wear and are NOT to be worn continuously (overnight).

Patient Signature

Date

Parent or Guardian Signature (if patient is under 18 years)

Date

Optometric Intern Signature

Date

Attending Doctor Signature

Date



Forest Grove Clinic  
(503) 357-5800

Downtown Portland Clinic  
(503) 224-2323

## Informed Consent for Continuous Wear (Overnight) Contact Lenses

**Welcome to Pacific University's College of Optometry Family Vision Center!!**

Continuous wear (overnight) contact lenses represent an exciting and convenient means for the correction of refractive error. A thorough ocular examination assessing eye health, eyeglass prescription, and your suitability for contact lens wear must be performed prior to the dispensing of contact lenses. It is important to realize that the U.S. Food and Drug Administration classifies contact lenses as medical devices. As with many medical devices, certain risks may be associated with their improper use and maintenance.

Since you will be wearing these lenses for extended periods, it is very important to follow your doctor's recommendations for wearing time, lens replacement schedule, cleaning and disinfection, and frequency of follow-up visits. Failure to comply with proper lens care procedures and periodic follow-up examinations may result in potentially serious ocular complications that may lead to permanent eye damage and vision loss. By following the procedures outlined by your doctor, the chances of developing a complication are greatly minimized.

**IN THE BEGINNING IT IS NORMAL IF YOU EXPERIENCE THE FOLLOWING:**

- YOUR EYES ITCH OR FEEL FUNNY WHILE WEARING THE LENSES.
- ONE LENS IS MORE NOTICEABLE THAN THE OTHER.
- YOUR VISION SEEMS FUZZIER THAN GLASSES.
- ONE EYE SEES BETTER THAN THE OTHER.
- YOU HAVE TROUBLE HANDLING YOUR LENSES.

**REMOVE YOUR LENSES IMMEDIATELY IF YOU EXPERIENCE ANY OF THE FOLLOWING:**

- UNUSUAL EYE PAIN
- EXTREME SENSITIVITY TO LIGHT
- EXTREME REDNESS OF THE EYE
- DAMAGE TO OR EXCESSIVE DRYNESS
- PROLONGED A LENS
- EXCESSIVE TEARING BLURRY OR UNCLEAR VISION
- UNUSUAL CLOUDY OR FOGGY VISION
- YOU SUSPECT SOMETHING IS WRONG

**Contact Lens Care**

Proper care is necessary for successful wear, normal lens life, and good eye health. You will be provided with products with which you will clean, disinfect, and store your lenses. The following products should be utilized for your lenses:

Care System \_\_\_\_\_

Re-wetting \_\_\_\_\_

It is very important to correctly follow the lens replacement schedule prescribed by your doctor:

Replace Lenses \_\_\_\_\_

Discontinuing lens wear after experiencing these symptoms should provide relief. If these symptoms persist after lens removal, you should immediately call for an appointment or consultation with your eye care practitioner who will provide the necessary treatment. In the event you are unable to contact our clinic at the above listed numbers, contact another eye practitioner or the nearest hospital emergency room.

**BY SIGNING BELOW I AGREE THAT:**

I understand that I am being fit with continuous wear (overnight) contact lenses and that my cooperation and compliance is vital to the success of their use. I have been told of the possible risks and consequences associated with extended wear lenses. I am aware that there are other means of visual correction such as spectacles or daily-wear contact lenses that may represent less ocular risks. I will notify the eye clinic immediately if any eye or vision problems occur, or if I am unable to reach the clinic, I will call an eye doctor immediately. I have been instructed in proper contact lens care and handling procedures. I agree to abide by the wearing schedule and care regime outlined to me by my doctor and I understand the importance of maintaining regularly scheduled examinations for the health of my eyes. I have read and understand the above information. My intern and attending doctor have answered all my questions regarding this agreement and my responsibilities associated with contact lens wear satisfactorily.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent or Guardian Signature (if patient is under 18 years)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Optometric Intern Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Attending Doctor Signature

\_\_\_\_\_  
Date

## Informed Consent for Orthokeratology

### Welcome to Pacific University's College of Optometry Family Vision Center!!

Orthokeratology represents a means for non-surgical correction of refractive error. A thorough ocular examination assessing eye health, eyeglass prescription, and your suitability for contact lens wear must be performed prior to dispensing of contact lenses. It is important to realize that the U.S. Food and Drug Administration classifies contact lenses as medical devices. As with many medical devices, certain risks may be associated with their improper use and maintenance. A small percentage of contact lens wearers may develop potentially serious ocular complications that could result in permanent vision loss. By following the procedures outlined by your doctor, the chances of developing a complication are minimized. It is very important to follow your doctor's directions for wearing time, lens replacement schedule, cleaning and disinfection, and frequency of follow-up visits

The time required for successful orthokeratology will vary depending on your cornea's flexibility and your ability to adapt to the contact lenses. Special contact lenses will be worn at night to reshape the cornea and thus change the refractive error of the eye. There is no guarantee of the success of your orthokeratology treatment. Success will be dependent on your compliance, flexibility of your cornea, refractive error, contact lens hygiene, and your ability to keep your follow-up appointments. Keeping your appointments is crucial to the success of orthokeratology. Active treatment time may increase if appointments are missed. Orthokeratology is not permanent. After the active treatment period, a retainer contact lens will be needed to maintain your vision correction. Orthokeratology provides a non-surgical and reversible means for the correction of refractive error. Alternatives to orthokeratology include conventional contact lenses, refractive surgery and glasses.

**IN THE BEGINNING IT IS NORMAL IF YOU EXPERIENCE THE FOLLOWING:**

- YOUR EYES ITCH OR FEEL FUNNY WHILE WEARING THE LENSES.
- ONE LENS IS MORE NOTICEABLE THAN THE OTHER.
- YOUR VISION SEEMS FUZZIER THAN WHEN WEARING GLASSES.
- ONE EYE SEES BETTER THAN THE OTHER.
- YOU HAVE TROUBLE HANDLING YOUR LENSES.

**REMOVE YOUR LENSES IMMEDIATELY IF YOU EXPERIENCE ANY OF THE FOLLOWING:**

- UNUSUAL EYE PAIN
- EXTREME SENSITIVITY TO LIGHT
- EXTREME REDNESS OF THE EYE
- DAMAGE TO A LENS
- EXCESSIVE TEARING OR EXCESSIVE DRYNESS
- UNUSUAL CLOUDY OR FOGGY VISION
- YOU SUSPECT SOMETHING IS WRONG

**Contact Lens Care**

It is very important to correctly follow the care regimen prescribed by your doctor. Proper care is necessary for successful wear, normal lens life, and good eye health. You will be provided with products with which you will clean, disinfect, and store your lenses. The following products should be utilized for your lenses:

Care System \_\_\_\_\_

Re-wetting \_\_\_\_\_

Discontinuing lens wear after experiencing these symptoms should provide relief. If these symptoms persist after lens removal, you should immediately call for an appointment or consultation with your eye care practitioner who will provide the necessary treatment. In the event you are unable to contact our clinic at the above listed numbers, contact another eye practitioner or the nearest hospital emergency room.

**BY SIGNING BELOW I AGREE THAT:**

I have read and understand the above and agree to participate in the orthokeratology program prescribed for me. I understand that I am being fit with nightly wear orthokeratology lenses and that my cooperation and compliance is vital to the success of their use. I understand the goals of orthokeratology and limitations of orthokeratology. I understand that my lenses are designed solely for overnight wear and are NOT to be worn continuously (daytime). I have been told of the possible risks and consequences associated with contact lens wear. I am aware that there are other means of visual correction such as spectacles that may represent less ocular risks. I will notify the eye clinic immediately if any eye or vision problems occur, or if I am unable to reach the clinic, I will call an eye doctor immediately. I have been instructed in proper contact lens care and handling procedures. I agree to abide by the wearing schedule and care regime outlined to me by my doctor and I understand the importance of maintaining regularly scheduled examinations for the health of my eyes. I have read and understand the above information. My intern and attending doctor have answered all my questions regarding this agreement and my responsibilities associated with contact lens wear satisfactorily.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent or Guardian Signature (if patient is under 18 years)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Optometric Intern Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Attending Doctor Signature

\_\_\_\_\_  
Date