

1 **Board of Medicine and Osteopathic Medicine**
2 **Ophthalmology Informed Consent Committee**

3
4 **DRAFT MINUTES**

5
6 **Wyndham Tampa Westshore**
7 **700 N Westshore Blvd**
8 **Tampa, FL 33609**
9 **(813) 289-8200**

10
11 **November 7, 2011**
12

13
14 Roll Call 4:30 p.m.

15
16 **Members Present:**

17 Nabil El Sanadi, M.D., Chair
18 Donald Mullins, MD Consumer Member
19 Ana Hayden, D.O.
20 Rina Malan, DO Consumer Member

21
22 **Members Absent:**

23 Elisabeth Tucker, M.D.

24
25 **Staff Present:**

26 Joy A. Tootle, J.D., Executive Director
27 Ed Tellechea, Board Counsel
28 Donna McNulty, Board Counsel
29 Nancy Murphy, Paralegal
30 Whitney Bowen, Regulatory Specialist II

31
32 **Others Present:**

33 Dr. Stephen G. Schwartz, FL Soc. of Opth.
34 Dr. James Rowsey, FL Soc. of Opth

35
36 Dr. El Sanadi explained that the committee was emailed a draft consent form which included Dr. Bizer's suggestions in red font and Dr. Alfonso's suggestions in blue font. Dr. El Sanadi led the committee through a review of the proposed document section by section to discuss the suggestions.

37
38 Dr. Hayden requested that at the top of page 1 the first question be amended to "Does the patient need or want a translator, interpreter or reader?". The committee unanimously agreed to the addition of the word "reader".

39
40 Dr. El Sanadi clarified that the approved form would be voluntary for practitioners to use. Individual physicians can modify the form for their own practice. Mr. Mullins reminded the committee that if a physician modified the form, that physician would not be afforded the protections set forth in the statute. Mr. Tellechea agreed. If physicians used the approved form without revision, they are protected.

41
42 On page 2 of the proposed form, the word "distance" was added before vision in the second full paragraph per Dr. Bizer's suggested and the committee adopted that amendment.

43
44 On page 3, under the first paragraph under the heading "What are the Recognized Risks of Cataract Surgery" the Committee adopted Dr. Alfonso's suggestions in blue font with the addition of "(fragments)" as recommended by Dr. Bizer by a vote of 3-1.

1 In the second paragraph in that section, a motion was made to change the first sentence to:
2 “The specific, recognized, risks of a Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK),
3 if performed in conjunction with cataract surgery are similar to those for cataract surgery, but also
4 include perforation to the cornea, damage to the iris, increased astigmatism, and scarring, which could
5 cause loss of vision.” This change was approved unanimously.
6

7 On page 4 of the proposed form, under the heading, “Other Risks from Cataract Surgery”, the
8 Committee voted 3-1 for the following amendment in the second sentence of the first paragraph:
9

10 “Local anesthesia may affect or damage to the retina, the optic nerve and may lead to: bleeding behind
11 the eye, double vision, and permanent vision loss, perforation of the eye, cardiopulmonary
12 complications, and in rare cases coma or death.”
13

14 In the last paragraph under this same section, Dr. Alfonso’s suggestions in blue were adopted by the
15 committee with the amendment of adding “known” before the words “medical conditions”.
16

17 Under the section “What Are My Out of Pocket Costs” the Committee approved all of Dr. Bizer’s
18 changes in red with the addition of the word “your” before cataract removal.
19

20 Mr. Mullins commented that the end of the form there should be an additional acknowledgment that an
21 adverse outcome could be reported to the Board of Medicine or Board of Osteopathic Medicine. After
22 discussion, the Committee declined to include language to that affect.
23

24 The following language was approved by a vote of 2-1 to conclude the form on pages 5 and 6:
25

26 **PATIENT’S ACCEPTANCE OF RISKS:**

27 **I have read this informed consent (or it has been read to me) and I fully understand it and the**
28 **possible alternatives to cataract surgery, the risks, complications, and benefits that can result from**
29 **that surgery.**

30 By signing below, I (we) certify that this form has been fully explained to me (us) , that I (we) have
31 filled in all the blank spaces, and that my ophthalmologist has answered all of my (our) questions, and I
32 (we) understand and accept the risks, benefits, and understand the alternatives of cataract surgery.
33

34 The surgery is on my _____RIGHT EYE _____LEFT EYE
35

36 _____ I am aware of the recognized specific risks related to cataract surgery that are described in
37 this form.
38

39 _____ I am aware that no intraocular lens is perfect, and that I may still need to use glasses or
40 contacts for at least some activities or in low light regardless of the type of lens implanted. I am aware
41 that no intraocular lens calculation is perfect, and that it is more difficult in an eye that has had prior
42 corneal surgery or retinal or glaucoma surgery. I am also aware that the intraocular lens may later need
43 to be repositioned, replaced, or removed by way of a subsequent surgical procedure.
44

45 On the advice of my Ophthalmologist, he/she and I choose the following premium lenses:

46 _____Multifocal Intraocular Lens

47 _____Toric Intraocular Lens

48 _____Accommodative Intraocular Lens

49 _____Monofocal/Monovision lens (Right eye near/distance; Left eye near/distance).

50 _____Other_____

1
2 _____ I understand that if during surgery, my ophthalmologist is unable to use any of the premium
3 lenses; I consent to the implantation of a Monovision Intraocular Lens.

4
5 _____ I am aware of the recognized specific risks related to Limbal Relaxing Incision (LRI) or
6 Astigmatic Keratectomy (AK) for Astigmatism Reduction are those that are described in this form, and I
7 understand that any of these risks could result in loss of vision, blindness or loss of the eye, and may
8 require me to undergo further surgery. Furthermore, the LRI or AK may not fully correct the
9 astigmatism, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

10
11 _____ On the basis of the above statements, I voluntarily consent and authorize this cataract
12 surgery procedure.

13
14 **Patient Print Name:** _____

15 **Patient Signature:** _____

16 **Date:** _____ **Time:** _____

17 **(Or person authorized to sign for patient)**

18 **Witness Print Name:** _____

19 **Witness Signature:** _____

20 **Date:** _____ **Time:** _____

21 **Surgeon Print Name:** _____

22 **Surgeon Signature:** _____

23 **Date:** _____ **Time:** _____

24
25
26 Dr. El Sanadi expressed appreciation to all the contributors to the form including Dr. Bradley Fourake,
27 Dr. Eduardo Alfonso, Dr. William Driebe, and Dr. Wayne Bizer. He stated he would send a letter of
28 thanks to those individuals on behalf of the Committee.

29
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31 The meeting adjourned at 6:01 p.m.