

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

4  
5 **Wyndham Tampa Westshore**  
6 **700 N Westshore Blvd**  
7 **Tampa, FL 33609**  
8 **(813) 289-8200**

9  
10 **September 29, 2011**

11  
12  
13 Roll Call 3:00 p.m.

14  
15 **Members Present:**

16 Nabil El Sanadi, M.D., Chair  
17 Elisabeth Tucker, M.D.  
18 Donald Mullins, MD Consumer Member  
19 Ana Hayden, D.O.

20  
21 **Members Absent:**

Rina Malan, DO Consumer Member

22  
23 **Staff Present:**

24 Joy A. Tootle, J.D., Executive Director  
25 Ed Tellechea, Board Counsel  
26 Donna McNulty, Board Counsel  
27 Nancy Murphy, Paralegal  
28 Crystal A. Sanford, CPM, Program Operations Administrator

29  
30 **Others Present:**

31 Dr. El Sanadi took public testimony regarding the proposed informed consent form.

32 Bradley Fouraker, M.D. addressed the Committee and thanked Tully Patrowicz and Dr. El Sanadi for  
33 the collaboration on the form. He stated it was a patient safety document that needs to be easy to read  
34 and understand and prompt the patient to ask questions.

35 Dr. Hayden questioned the use of translator instead of interpreter. She also asked if anything needed to  
36 be included in the form regarding after care.

37 Dr. El Sanadi stated it did not need to be included in the form.

38  
39 Dr. Fouraker agreed and stated there were laws concerning after care for optometrist's and  
40 ophthalmologists that include separate informed consents.

41  
42 Dr. El Sanadi suggested reviewing the proposed form line by line.

43  
44 Bruce Lee (phonetic), Esquire was introduced as the General Counsel for the Florida Society of  
45 Ophthalmology and was present with Dr. Fouraker.

46  
47 Dr. El Sanadi went back to the issue of translator or interpreter and the Committee agreed to use both.  
48

1 Ms. McNulty suggested adding “want” to the question so that it reads, “Does the patient need or want a  
2 translator or interpreter?” The Committee agreed.

3  
4 The Committee agreed to add the following sentence to the “To The Patient” paragraph:

5  
6 *This disclosure is not meant to scare or alarm you; it is simply an effort to make your better informed so*  
7 *that you may give or withhold your consent to cataract surgery **procedure and** should reflect the*  
8 *information provided by your surgeon.*

9  
10 Dr. Fouraker pointed out typographical errors in the paragraph entitled, “Alternative Treatments”.

11  
12 Dr. Hayden stated the word “mandatory” needed to be removed from the title of the form. The  
13 Committee agreed.

14  
15 Mr. Mullins had concerns regarding the font used for the form as it related to the term “intraocular lens  
16 or IOL” as it was currently written in the form because of the potential confusion of ‘I’ or ‘l’ in the age  
17 of texting.

18  
19 Dr. Fouraker pointed out ‘lens’ needed to be ‘lenses’ in the paragraph entitled, “How Will Removing the  
20 Cataract Affect My Vision?”. The Committee agreed.

21  
22 In the same paragraph, Ms. McNulty pointed out there needed to be a comma between the words  
23 “vision” and “many”. The Committee agreed.

24  
25 Dr. El Sanadi stated the word “lenses” needed to be added to the third paragraph of the section entitled,  
26 “What Are the Types of Intraocular-Lenses (IOL) That Are Available to Me”.

27  
28 Dr. Fouraker suggested adding language to the second paragraph under the same section:

29  
30 “ . . . some may find it uncomfortable, which may require compensating glasses, contact lenses, or  
31 another operation to change the IOL.”

32  
33 The Committee agreed to this addition.

34  
35 Dr. El Sanadi stated the word “or” needed to be added to the first paragraph of the section entitled,  
36 “What are the Recognized Risks of Cataract Surgery?” between “a droopy eyelid,” and “double vision”.  
37 The Committee agreed,

38  
39 Dr. Fouraker suggested adding additional risks.

40  
41 Mr. Mullins expressed concern about the balance of true outcomes and side effects against a physician  
42 practicing below the standard of care.

43  
44 Dr. Fouraker stated he felt it would be negligent not to tell the patient.

45  
46 Dr. El Sanadi asked him to clarify what percentage of these risks were true risks versus the skill of the  
47 physician or are there unskilled physicians that would have a higher risk for these side effects.

48  
49 Dr. Fouraker stated each risk as an individual risk is less than one percent.

1 Mr. Mullins questioned whether death should be added then since it is a possibility when going under  
2 anesthesia.  
3  
4 Dr. Hayden asked if medical conditions put patients at greater risk and whether that information should  
5 be included on the form.  
6  
7 Dr. El Sanadi stated another portion of the form addressed those issues.  
8  
9 Continuing in the same section, Dr. Fouraker suggested adding the following language:  
10  
11 “ . . . , double vision; displacement of the lens, or portions of the lens; displacement of the vitreous; and  
12 injury to the cornea, iris, pupil function, or other parts of the eye”.  
13  
14 The Committee agreed to the addition of this language.  
15  
16 Mr. Mullins expressed concern about “or other parts of the eye” stating it was vague.  
17  
18 Dr. Fouaker suggested changing the wording to state the following in lieu of “or other parts of the eye”:  
19  
20 sclera, conjunctiva, the operation itself, or pieces of the lens that cannot be removed.”  
21  
22 The Committee agreed so the final language reads:  
23 “ . . . , double vision; displacement of the lens, or portions of the lens; displacement of the vitreous; and  
24 injury to the cornea, iris, pupil function, sclera, conjunctiva, the operation itself, or pieces of the lens  
25 that cannot be removed.”  
26  
27 Mr. Mullins had concerns about language in the third paragraph of this section where it says, “depending  
28 on his judgment”. He felt this language gave the physician too much leeway from what the patient  
29 consented.  
30  
31 Mr. Tellechea expressed concern regarding Dr. Fouraker’s suggested language regarding leaving a  
32 portion of the lens. He said there are laws to prohibit leaving a foreign object in the patient.  
33  
34 Dr. El Sanadi suggested having Department of Health experts review the form before it is finalized.  
35  
36 Dr. Fouraker introduced Dr. James Rowsy (phonetic), Department Chair of the University of South  
37 Florida.  
38  
39 The Committee agreed to replace “depending on his judgment” with “or as agreed to on pages four and  
40 five”.  
41  
42 Dr. Fouraker suggested adding damage to ocular muscles to the risks.  
43  
44 Dr. El Sanadi stated he felt that was covered under “nearby structures”.  
45  
46 Dr. Hayden stated she was not sure if the section on other medical conditions was necessary.  
47  
48 Dr. El Sanadi stated the section was added to encourage the patients to discuss their medical conditions.  
49

1 Dr. Fouraker suggested adding possible cardiorespiratory problems under the section entitled, “Other  
2 Risks From Cataract Surgery”.

3  
4 The Committee agreed and the new language reads:

5  
6 *Local anesthesia may affect or damage nearby structures, and lead to additional complications.*  
7 *Examples include bleeding behind the eye, or double vision and possible cardio-respiratory*  
8 *complications.*

9  
10 Dr. Fouraker suggested adding perforation since it is a known complication for anesthesia to then eye.

11  
12 Dr. El Sanadi stated he felt that was covered under “nearby structures”.

13  
14 Dr. Hayden asked what “Other” was considered under the section “Patient’s Acceptance of Risks”.

15  
16 Dr. Fouraker stated it just referenced another type of lens option.

17  
18 Mr. Mullins expressed concern regarding the following:

19  
20 *I realize that although this is my preference, my ophthalmologist may not be able to implant that lens at*  
21 *the time of surgery.*

22  
23 He thought this was too broad and gave the physician too much ability to change the surgery without the  
24 patient’s consent.

25  
26 After much discussion, it was agreed the types of lens listed in the form would be formatted differently  
27 with the following statement:

28  
29 \_\_\_\_\_ *I understand that if during surgery my ophthalmologist is unable to use any of the premium*  
30 *lenses, I consent to the use of the following:*

31  
32 Dr. Hayden asked if retained suture is a common side effect.

33  
34 Dr. El Sanadi stated it was.

35  
36 Dr. Hayden stated the form was several pages long and suggested having the patient initial and to date  
37 each page at the bottom.

38  
39 The Committee agreed.

40  
41 Dr. El Sanadi stated he wanted a Department expert to review the form before the Board finalizes it and  
42 asked if Dr. Hayden would do the same with an Osteopathic expert.

43  
44 Dr. Hayden stated that she would.

45  
46 Mr. Tellechea stated that the rule language was drafted and incorporated the rule by reference. He said  
47 this form will be presented to the Board at the meeting tomorrow and then a Department expert will  
48 review it. Afterwards, the form will be presented the Board at the December Board Meeting for final  
49 approval. Similar arrangements were made for the Osteopathic Board.

50  
Report prepared by Crystal Sanford

- 1 Dr. El Sanadi thanked Dr. Fouraker for his assistance.
- 2
- 3 The meeting adjourned at 4:44 p.m.