

**THE FOLLOWING TOPICS MUST BE DISCUSSED IN THE CONSENT. THESE ARE SOME SUGGESTED STATEMENTS**

▪ INTRODUCTION:

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

▪ CONFIDENTIALITY

1) STUDY NEI/NIH

The New York Eye & Ear Infirmary will take all reasonable measures to protect the confidentiality of your records. Your identity will not be revealed in any publication that may result from this study. The confidentiality of your records will be maintained to the fullest extent possible. Absolute confidentiality cannot be guaranteed, since research documents are not protected from subpoena. Your medical record, including identifying information, may be inspected and/or photocopied by officials of the Food and Drug Administration, the National Eye Institute or other federal or state government agencies during the course of carrying out their functions.

2) DRUG SPONSOR

Information from this study will be given to the sponsor. It will also be given to the United States Food & Drug Administration (FDA). It may be given to governmental agencies in other countries where the study drug may be considered for approval. Medical records which identify you and the consent form signed by you will be looked at and/or copied for researcher regulatory purposes by the FDA, the Department of Health and Human Services (DHHS) agencies, governmental agencies in other countries, and the Institutional Review Board responsible for this study.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in these presentations.

**In contact section: "For questions regarding your rights as a research subject, contact Joseph B. Walsh, MD - Chair, NYE&EI Institutional Review Board at 212-979-4447."**

To avoid having unnecessary re-writes of consent forms, please prepare them with these pointers in mind:

- Write consent forms in the second person, that is, use "you" and "your", not "I agree to..." or "I understand..."
- Use headings: Purpose of Study, Participation, Risks and Discomforts, Benefits, Alternatives, etc. **Be sure to spell out procedures so subject can fully understand.**
- Avoid scientific and medical jargon or measurements.
- Delete language supplied by study sponsors that duplicates or contradicts Infirmery "boilerplate" language

**Always include direct phone number to reach Principle investigator for questions and emergencies. DO NOT USE NYEEI GENERAL PHONE NUMBER.**

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- Include **PATIENT QUESTIONNAIRE** on signature page of consent. **THE PATIENT QUESTIONNAIRE CANNOT BE ALTERED.**
- **Date each page and include version number (version number 1 if original) and number all pages.**

### **PATIENT QUESTIONNAIRE**

I have read this consent form and have discussed it with (Fill in Investigator's name) for the procedure(s) described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. **I understand that any future questions that I might have will be answered to my satisfaction. I have been given a copy of the signed consent form.**

I understand that I will be informed of any new findings developed during the course of this randomized study. The investigator may withdraw me from this research if circumstances arise which warrant doing so.

By **initialing** below **after each statement**, I agree that I

- a) Have understood the consent form A \_\_\_\_\_
- b) Have had the opportunity to ask questions and discuss this study B \_\_\_\_\_

- c) Have received satisfactory answers to all my questions C \_\_\_\_\_
- d) Have received enough information about this study D \_\_\_\_\_
- e) Understand I am free to leave the study at any time without having to give a reason and without affecting my medical care E \_\_\_\_\_
- f) Understand that my medical records may be reviewed by the company sponsoring the study and by government authorities F \_\_\_\_\_

**IF YOU CAN NOT INITIAL ANY OF THE SIX QUESTIONS LISTED ABOVE,  
YOU SHOULD NOT SIGN THIS CONSENT FORM**

**THIS MUST BE INCLUDED WITH THE SIGNATURE PAGE OF YOUR CONSENT FORM  
(Before signatures)**

**NOTICE: A COPY OF CONSENT FORM MUST BE E-MAILED TO THE IRB OFFICE AT [rjordan@nyee.edu](mailto:rjordan@nyee.edu) BEFORE MEETING AS COMMITTEE MUST GET A COPY TO REVIEW BEFORE MEETING.**

**For more information regarding consent forms, please go to:  
<http://www.hhs.gov/ohrp/policy/index.html#informed>**

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<sup>1</sup> Revised 9/07