

**THE NEW YORK EYE & EAR INFIRMARY  
INSTITUTIONAL REVIEW BOARD  
DIRECTIONS FOR SUBMITTING A COMPLETE PROTOCOL FOR REVIEW**

Fill out all applicable sections of the attached forms and submit (no later than **14** days/10 business days before committee meets) with the items required below. Number all attachments to the Protocol Statement consecutively in the order given here. There are generally seven parts to a complete protocol submission. These are: **1) Abstract, 2) Discussion, 3) IRB statement, 4) Financial Disclosure form, 5) Consent form, 6) Research authorization form, 7) Sponsor company's protocol (if company sponsored) with all attachments, including Sponsor Letter or Business Associate Agreement (see attached).** Each separate document should have the version number (number 1 if first submission) and each page numbered and dated.

**NOTE: THE PRINCIPAL INVESTIGATOR OR CO-INVESTIGATOR MUST PRESENT HIS/HER PROTOCOL AT IRB MEETING. ALL FORMS AND INSTRUCTIONS ARE AVAILABLE ON THE INFIRMARY'S INTRANET AT <http://intranet.nyee.edu> AND WEB-SITE AT [www.nyee.edu](http://www.nyee.edu) .**

**IRB FEES: For all sponsored (private or govt.) protocols the following fee schedule applies:**

**NEW PROTOCOL REVIEW: \$1,250.00 RENEWAL : \$250.00**

**The fees must be paid at time of submission. No protocol will be accepted without payment. The PI may request a waiver, in writing, from the IRB chair if non-funded. Please include your waiver request with your submission**

- 1) An abstract of the protocol, entitled '**ABSTRACT**', written in lay terminology. In writing the abstract, investigators must keep in mind that Board members are not necessarily technically knowledgeable in all fields. Please be sure to include all pertinent information including the number of subjects to be enrolled.
- 2) A discussion section, entitled '**DISCUSSION**' must give complete information concerning the following items. Be sure to include each item presented and lettered consecutively exactly as given below. If any item does not apply to proposed activity, type N/A (Not Applicable) by that item letter.
  - A) The objectives or specific aims of the project and a complete, concise description of the methodology.
  - B) The Nature of the contact with human subjects.
  - C) An explanation of how subjects will be selected (including the number of subjects, their ages, sex and other relevant characteristics).
  - D) A discussion of literature or other data supporting the contention that the proposed procedure(s) is/are relatively safe as opposed to unproved, uncommon or extra-

hazardous ones. The investigator should also include statements, where applicable, concerning the effectiveness of the proposed procedure as compared with alternative treatments that could be used.

- E) A statement giving the dosage or amount of radiation subjects will receive.
- F) An explanation of the manner for debriefing subjects about the research when their participation has been terminated.
- G) A discussion of the principal investigator's qualifications to conduct the proposed research (e.g., degrees earned, recent related research, publication titles). **Note: All persons involved must present proof that he/she has attended a course on the protection of human subjects in research. The NIH offers a 45 minute on-line course with a printable certificate of completion at <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>**
- H) Names and titles of those obtaining informed consent (only if different from those named in the investigator section on the first page of the protocol statement).

**The following must also be included:**

- A copy of all surveys and other test instruments to be used.
  - A copy of the cover letter that will accompany the test instrument.
  - If a study will be conducted at an institution other than NYEEI, a letter stating that the institution is aware of the study and approvals must also accompany the application.
- 3) The **IRB Statement** must be filled out completely and include names and contact information of all investigators and any person having contact with subjects and data. All persons having contact with subjects or data must show proof of training **List Principal Investigator (PI) First. \*Residents, Fellows and Students cannot be listed as PIs. The only exception is a Fellow with admitting privileges at the Infirmary.**
  - 4) A **Financial Disclosure** must be made by the Investigator(s). The purpose of this information is to have full disclosure of any financial or quasi-financial agreements that could influence the research. The IRB responsibility is to assure that all participants in research at the Infirmary have their rights rigorously respected and protected. **(Use attached form)**
  - 5) A copy of **Consent** and/or assent forms in the **language of the subject (an electronic version of consent must be sent to IRB at least 2 weeks prior to meeting in order for committee to review before meeting – the committee will not vote on any consent or revised consent that was not submitted 2 weeks in advance of meeting)**. Explain, in plain language **(The Federal Government states that the average research subject**

reads at a 5<sup>th</sup> grade reading level and all consents should be worded with this in mind), all scientific and medical terminology, procedures, risks, benefits, alternatives and duration and include number of subjects to be enrolled. (See suggested language for use in preparing your consent form). The consent form will be a separate document from the protocol and pages should be numbered as such (please date document and include IRB number, which can be obtained from the IRB coordinator, as well. **AMENDMENTS/REVISIONS:** Any subsequent changes to document must be labeled Version #2,3,4,etc with new date and IRB number on each page. **Consent must contain name and phone number of IRB Chair (Joseph B. Walsh, MD, 212-979-4447), PI Phone number and patient questionnaire (see attachment). If consent form is other than English, a statement from the translating company or individual attesting to his/her qualifications and accuracy of translation, including all scientific terms, must be included.**

- 6) The Health Insurance and Portability and Accountability Act of 1996 and implementing regulations ("HIPAA") requires that each subject in an interventional clinical research study must sign a completed **Research Authorization form**. This form authorizes the use and disclosure of the subject's protected health information which includes all of the types of information listed on the attached sheet. Permissible uses of protected health information are limited to those listed in the Research authorization form. It is the responsibility of the Principal Investigator to ensure that the Research Authorization form covers all of the uses and disclosures necessary for the research study. **This form must have version number, date and IRB number printed on each page.**
- 7) **Sponsor Protocol**, including sponsor letter and all other attachments.

**Once you have submitted your complete protocol, the IRB COORDINATOR will check documents for completeness, and give to Chair/IRB members for review. ALL new or AMENDED CONSENT FORMS must also be sent to the coordinator by e-mail in order to distribute by email to the committee members for their review prior to meeting. All incomplete submissions will be returned to the investigator. Reviewer will contact investigator with any questions or changes needed before the IRB meeting. At the meeting, the PI or co-investigator will give a brief presentation to the committee and the committee will discuss and then vote. The committee will inform PI/co-I of it's decision by sending an approval/disapproval letter by mail. Please keep in mind that if your protocol is approved, it will only be approved for a maximum of one year from the date of approval and you must submit to the IRB a yearly report (use Annual Progress Report form) with request to renew (if so desired) for an additional year. The IRB, if it deems necessary, may request a report earlier than one year or may only renew for less than one year. You must also inform the IRB immediately upon termination of the study and give results of study by filling out annual progress form. If a report is not received by the IRB upon completion of the approval year (or period set by IRB), it will be deemed EXPIRED and no action may continue on protocol. Should the investigator wish to resume work on any EXPIRED or TERMINATED protocol, he/she must re-submit protocol as NEW along with all current,**

**updated paperwork as well as the IRB NEW PROTOCOL REVIEW fee. The IRB may take disciplinary action against the PI and all involved in the study including suspension of research privileges and termination of all studies involving investigators in question. As is required by the Federal government, all disciplinary action against an investigator must be reported to the proper authorities including the FDA and DHHS.**

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<sup>1</sup> REVISED 04/08