THE NEW YORK EYE AND EAR INFIRMARY

POLICIES AND PROCEDURES

FOR THE
PROTECTION OF HUMAN RESEARCH SUBJECTS

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THE NEW YORK EYE AND EAR INFIRMARY

Assurance of Compliance with DHHS Regulations For Protection of Human Research Subjects

I. Principles Governing the Use of Human Subjects in Research

The New York Eye and Ear Infirmary, a Hospital hereinafter referred to as NYEEI, has a mission to protect the rights and welfare of human research subjects and it gives assurance that this institution does and will continue to comply with Department of Health and Human Services regulations for the Protection of Human Subjects (21 CFR 50-56, as amended April 1, 2001). The research referred to herein is broad in scope, i.e., all the systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. This includes comparison of two or more diagnostic, therapeutic or preventive interventions to determine which is superior in research; this is the case even when said intervention is being compared and is in conformance with the accepted standards of customary medical practice. Clinical investigations and studies that involve retrospective chart review of medical records also fall under the category of research to be submitted to the IRB for review and approval. Also, the observation (including observation by participants) of public behavior, including where observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects and when either of the following additional conditions exist:

> (i) the observations recorded about the individual, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject financial standing or employability, or
>
> (ii) the research deals with sensitive aspects of the subject's own behavior, or use of alcohol. Projects that involve any one of the above conditions may be referred to the IRB for review on a case-by-case basis.

For purposes of compliance, this assurance covers only those researchers and research activities involving human subjects at NYEEI or research sponsored by the NYEEI, or conducted under any employee or agent (including voluntary status) in connection with his/her institutional responsibilities.

II. Statement of Policies and Procedures Governing Research Involving Human Subjects

A. POLICIES

NYEEI policies and practices governing all research activities, regardless of source of support, are guided by the ethical principles as set forth in the following: The Nuremberg Code, The Declaration of Helsinki, 1964, AMA Ethical Guidelines for Clinical Investigation, 1966 and, in particular, for matters requiring current interpretation, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report") of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979.

1. The NYEEI IRB is a Committee of the Medical Board. Its members and Chairperson(s) are selected by said Board whose terms are renewed annually as is stated in the by-laws of the Medical Board. An annual report is submitted to the Medical Board and to the Medical Staff at the Annual Meeting. No other action by the Medical Board occurs. For Hospital administrative purposes, the President and CEO also receive a copy of the minutes of each meeting.

2. The overriding principle freely adopted and widely communicated within NYEEI, is that no research shall expose human subjects to the risk of unreasonable harm. In addition, no research shall expose subjects to any risk that reasonably can be avoided.

3. The Principal Investigator of each project has primary responsibility for determining whether the subjects will be exposed to procedures exceeding what is customary risk of harm in the standard practice of medicine. IRB review and approval is required, unless the activity is exempted from this requirement. If there is reason for uncertainty about whether the research requires review, the investigator shall seek the advice of the Chairman of the IRB. The principal investigator also has primary responsibility for protecting subjects from being harmed by their participation in the research. All others involved in the conduct of the study share this responsibility. All investigators involved in research must provide the IRB with proof of training in a protection of human subjects in research course. **FINANCIAL STATEMENTS IN IRB SUBMISSION-LIABILITY**

   If Financial Dosclosure form is inaccurate or left blank when there is remuneration to PI related to the study then the IRB cannot judge if the patient, who has a right to full disclosure, is correctly and properly informed related to inducements that could alter

consent. The result is that the IRB cannot judge if the protocol meets the criteria for approval or the PI getting $$ (direct or indirect) beyond what is reasonable so judgment questioned – e.g. a PI is getting $$ (travel, consultant or other fees or $$ for assistants etc.) and this is not disclosed, then the IRB approval would be faulty due to inadequate information.

4. The IRB shall be authorized to review and to approve or disapprove, or state conditions for, the conduct of any research involving a human subject or subjects in accordance with the policies stated herein. The membership of the IRB shall be chosen with a view to its ability to represent credibly the varying perspectives of subjects, investigators and society-at-large. The IRB will maintain up-to-date CVs and other appropriate material, if deemed necessary, to assure appropriate representation. The roster will identify the member, scientific and non-scientific by earned degree, representative capacity and experience/expertise.

5. The principal investigator, or other qualified person, shall obtain the consent from the subject in the format authorized by the IRB prior to patient participation. Investigators shall not use individuals as subjects unless satisfied that they, or others legally responsible for their well being, consent to participation freely and with awareness of the objectives of the research, the procedures to be followed, and the potential risks and benefits. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

   a. The research involves no more than minimal risk to the subjects;

   b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

   c. The research could not practicably be carried out without the waiver or alteration; and

   d. Whenever appropriate, the subjects will be provided with additional data pertinent information after participation. The consent form must incorporate the following:

   (1) The Food and Drug Administration reserves the right to inspect such records.

   (2) When research involves more than minimal risk, an explanation must be provided to subjects as to whether compensation and an explanation as to

whether medical treatments are available if injury occurs and, what they consist of.

6. Investigators and NYEEI shall respect the privacy of subjects. They shall protect confidential information given them, advising subjects in advance, as appropriate, of limits to their ability to ensure that the information will remain confidential. NYEEI has established a Privacy Office to adjudicate any issues related to these privacy issues, including HIPAA compliance.

7. Subjects shall not be induced to participate by means or circumstances that might affect their ability to decide freely.

8. It shall be made clear to subjects the consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject. They shall further be advised that such refusal or withdrawal will not result in any prejudice or loss of benefits to which the subject is otherwise entitled.

9. Staff members who assign or supervise research conducted by students are responsible for ensuring that the student is educated to safeguard adequately the well-being of the subjects. All student research involving human subjects shall be under the supervision of a staff member.

B. PROCEDURES

1. Those whose purpose it is to conduct, direct, or supervise research involving human subjects shall evaluate the undertaking and ensure that it is consistent with the policies and procedures stated herein.

2. All research involving human subjects conducted by members of the NYEEI must be reviewed and approved by the IRB before its initiation unless it falls into one of the following exempt classes of research activities:

    a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

    (i) Research on regular and special education instructional strategies, or

    (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement). If information is taken from these sources, it is to be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

c) Research involving survey or interview procedures except where all of the following conditions exist:

i) Responses are recorded in such a manner that the human subjects cannot be identified, directly or through identifiers linked to the subjects,

(ii) the subject's responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or

(iii) The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. Projects that involve any one of the above conditions may be referred to the IRB for review on a case–by-case basis.

(d) All research conducted by NYEEI staff and all research using the NYEEI facilities must have Departmental and IRB approval. The NYEEI IRB forms are available on the web at https://irbmanager.becirb.com. These forms must be completed in their entirety and submitted with the protocol and pertinent materials in a timely fashion on-line.

(e) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects is exempt from these regulations.

3. Review and approval of proposed research by the IRB may be required even if the proposal otherwise conforms to one of the exempt classes of research. For example, the advice of the IRB will be sought for procedures that deprive the subjects of necessary or accustomed services.

4. Investigators shall submit their plans for using human subjects to the IRB using the appropriate forms and according to the timetable established by the IRB to ensure orderly handling of its business. The IRB shall generally give approval only for the

specific research plan contained in the protocol presented to it, and for a definite period of time. No part of the plan that is relevant to the subjects shall be changed by the investigator, nor shall any subjects be used beyond the specified time, without further approval of the IRB unless necessary to eliminate apparent immediate hazards to human subjects.

5. Investigators shall immediately notify the IRB if they observe any life-threatening, or any significant adverse change in the health or behavior of a subject that may be attributable to the research and was not previously anticipated in the protocol. At the discretion of the IRB, the project may be suspended pending the outcome of an investigation. Any Serious Adverse Event (SAE) must be promptly reported to the IRB with verification that the accompanying documentation assures the same SAE has been reported to the proper authorities. If not, the IRB at the next meeting will inform the Administrator to forward said report to the proper authorities as well as the US Department of Health & Human Services and the Food & Drug Administration.
6. The IRB requests that all supporting documentation and updates from companies, granting agencies, and federal government be submitted to the IRB so that in multi-center trials or collaborative studies, the IRB is fully informed of all information requested for monitoring at NYEEI. In addition, the IRB reserves the right to monitor individual protocol compliance including but not limited to the informed consent procedure, mechanisms of the research and the research log books.

The New York Eye and Ear Infirmary Policies and Procedures for the Protection of Human Research Subjects shall be posted on the Infirmary's IRB web page and available to all staff. Members of the institutional community who are uncertain about whether their plans to conduct research involving human subjects are consistent with the policies and procedures of the institution are advised to consult with the IRB at 212-979-4447.

III. Implementation of Policies and Procedures Governing Research Involving Human Subjects

A. INTRODUCTION

Implementation may be modified on an on-going basis to accomplish optimally the policies and procedures governing research involving human subjects described in parts I and II of this assurance. All such modifications will be in accordance with 45 CFR, 46 and CFR 21:50, 54 & 56.

B. IRB PROCEDURES

The Institutional Review Board committee of The New York Eye and Ear Infirmary consists of individuals involved in research, nursing, pharmacy, social service, and clinical practice as well as members of the community.

1. The Institutional Review Board serves as a Committee for the protection of human subjects. At least eleven members, including scientific members, non-scientific members and non-affiliated members and unaffiliated community representatives are appointed by the Chairman of the Medical Board for a one-year renewable term. Additionally, the President and CEO serves as an ex-officio member.
2. A quorum consists of a majority of total membership, excluding those officially excused, provided that at least one scientific member and at least one non-scientific member are present and voting. All new protocols require a majority of the voting members; abstentions by participating voting members will be recorded.
3. The IRB agenda and new protocols, including consent forms are available to all members prior to each meeting. The agenda includes a summary of the protocols to be reviewed for new approval, renewal, termination, amendment, adverse event reporting or any other protocol related activity.
4. The investigator must submit all material to the IRB via the IRBManager web site. All protocols must be submitted to the IRB in at least two weeks preceding the meeting at which they will be considered. This is to allow for review by the chair or designee of the committee in advance of the meeting. In addition to the clinical protocol, an appropriate Abstract (written in lay terms), consent form, and Investigator Brochure (if applicable), and appropriate recruitment material must be included. The Abstract should be brief,

written for lay people and include a brief summary of any previous related animal or human experience. The Chair refers all appropriate research protocols to either full committee review or upon request from PI, conducts expedited review. The chair will not conduct expedite review if the item being submitted for expedited review does not meet the expedited review criteria.

5. Every protocol will be reviewed by the Chair and/or an experienced IRB member prior to the meeting at which it is discussed and voted upon. The reviewer is responsible for determining whether an investigation involves significant or non-significant risk and to convey that determination to the full IRB for its review. His/her job is to study and specifically evaluate the risks and benefits involved and to determine and report back to the IRB Chair and/or the full IRB if the risks and benefits are not spelled out sufficiently to assess the risk-benefit ratio. If the reviewers feel that they do not have enough expertise in the area the protocol covers then they can solicit help from the Chair or others with expertise in the relevant subject matter. Outside reviewers are not voting members of the IRB and therefore do not vote on any IRB actions or count towards a quorum.

With regard to surgical procedures, the risks and benefits are evaluated and then the benefit-risk ratio is determined; the stated risks of each protocol are also evaluated in comparison to the risks and potential benefits of alternative methods.

In relation to new drugs/instruments/devices, the protocol is to include the animal and human data when appropriate, so that the reviewer has a factual basis to begin the analysis.

For investigations involving new devices, instruments or treatments, the reviewer with or without expert guidance, is to determine the risk to the patient, similar to the fashion routinely utilized by physicians in their treatment of patients. When devices, instruments or treatments have potential side effects, the consent must note them. However, when the benefit to the subject is the only opportunity to save vision, for example, the benefit is to be carefully balanced with the risk and discussed fully at the IRB before consideration for approval. As always, any new treatment must be weighed against other available

potential treatment options. When the benefit is small and the risk great, then these studies must be evaluated particularly cautiously and approved only if the significant risk is reasonable after careful consideration.

In summary, in all cases the reviewer must determine the risk based on the data presented and weigh this against the proposed benefit. This information is then presented to the IRB for ultimate determination. The consent must reflect the above in plain language, without technical terminology, in layperson's, culturally sensitive language that can be understood by all potential participants. The determination of risk is one of the most important responsibilities of the IRB. The reviewer's summary will be sent to each member in advance of the meeting to facilitate informed discussion at the meeting.

The full committee will determine if there is need for review more before the minimum standard which requires a yearly review. While very few investigations involving greater than minimal risk devices come before the IRB, it is expected that these protocols will be reviewed at least every six months in accordance with the precedent set by the current committee. The Chair of the IRB may also have a protocol reviewed by an intramural consultant, knowledgeable in the project area, which may or may not be a member of the IRB.

6. Applications are presented for IRB review at the regularly scheduled meeting by the Principal investigator after it has been reviewed and approval by specific the department Chair, who has overall supervisory responsibility for projects in their respective departments. It is then reviewed by the Chair of the IRB and/or an intramural consultant knowledgeable in the project area who may or may not be a member of the IRB.
7. In accordance with and to the full extent of 45 CFR 46, 46.111 and CFR 21:50, 54, 56, risks to subjects are carefully weighed and the following are presented for deliberation by the IRB: Full protocol, consent form, consultant's review, investigator's response and additionally, for on-going studies, the number of subjects entered to date, any adverse effects and preliminary scientific results. Approval may be withheld when risks outweigh potential benefits. In many instances, modification of protocol must be made before final approval of a project is granted if the IRB requests. Special attention is given in instances where control subjects, minors, or other special populations whose

ability to give consent is in question, are included as part of the study. Protocols will not be accepted from any principal investigator or co-investigator who has delinquent or outstanding annual reports, continuing review submissions, updates, and outstanding payment of IRB review fees or termination materials.

8. Toxicity reports including preliminary results are required semi-annually, or at shorter intervals as the IRB rules appropriate, for projects in which experimental drugs or materials will be administered. More frequent reports may also be required from the PI in instances of new, non-standard use of approved drugs or devices if the IRB deems necessary.

9. IRB approvals, disapprovals, deferrals, and requests for clarifications or revisions are made in writing to the investigator or project director and in some cases, the chairperson of the responsible department. Files are to be maintained by the IRB on the IRBManager web site. Prompt responses to the Committee's concerns are required prior to the meeting so they can be presented for further IRB discussion. Investigators may be requested to meet with ad hoc subcommittees appointed or to appear personally at IRB meetings for a full discussion of their work and problems at hand. Project directors and principal investigators are informed and confirm in writing that they are under obligation to report to the IRB any unexpected emergent problems during the progress of their work or any planned major procedural changes.

10. The official NYEEI files are maintained by the IRB on the IRBManager web site accessible by username and password protected and include copies of the complete protocol as well as copies of all documents presented for review to the IRB and all transmittals between the IRB and the principal investigator.

11. The original signed copies of the IRB minutes are maintained by the IRB in a secure book. The minutes include time and place of meetings and a record of those present, a listing of all applications presented for review with the formal action taken by the IRB and a record of discussion of particular issues and their resolution. Minutes will be taken in accordance with 45 CFR 46.115 and CFR 21:50, 54, 56.

12. At the time of initial review, the full IRB will determine the frequency and extent of review of on-going projects appropriate to safeguard the welfare of human subjects involved. At the minimum, annual review of all projects involving human subjects will

be made. In the case of experimental drugs or materials, implants, state-of-the-art technology, review will be at six-month intervals or at closer intervals if the IRB so rules.

13. The NYEEI policy is communicated to investigators that changes in protocols relevant to human subjects, including instances in which the participation of human subjects is an added procedure to projects in progress, must be reviewed and approved by the IRB prior to implementation.

C. EXPEDITED REVIEW

The Chair or designated IRB member shall determine whether the research protocol meets the criteria necessary for an expedited review process. The eligibility of some research for review through the expedited procedure is in no way intended to negate or modify the policies of this institution or the other requirements of 45 CFR 46 and CFR 21:50, 54, 56. The IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

The only other research for which the IRB shall use an expedited review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories:

a. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays and microwaves).

b. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

c. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques. Voice recordings made for research purposes such as investigations of speech defects.

d. Moderate exercise by healthy volunteers.

e. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

f. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subject's behavior and the research will not involve stress to subjects.

g. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

h. Any other category specifically added to this list by DHHS and published in the Federal Register and accepted for expedited review by the IRB.

Expedited review shall be conducted by the IRB chairperson or by one or more of the experienced IRB members designated by the chairperson to conduct the review. In extraordinary circumstances and either a phone review, fax, email or calling of an extraordinary meeting of the full committee will occur to determine action on the expedited review. This protocol will be presented at the next stated IRB meeting. The IRB member conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. The reviewer may also refer other research protocols to the full committee whenever the reviewer believes that full committee review is warranted. Emergency-Compassionate use of an experimental device may be expedited on a case-by-case basis and reviewed/approved as above. In the case of emergency use of a test article, prior IRB review is not required, provided that the use is reported to IRB within five days. Any use thereafter is subject to prior IRB review.

D. INFORMED CONSENT

The IRB will determine the appropriate consent to be obtained in view of the circumstances of the project and the risks to the subjects. The NYEEI policy for obtaining informed consent is in accordance with 21 CFR 50.25 and that informed consent shall consist of at the minimum, the basic elements written in lay terms and at a 5th grade reading level of comprehension, as follows:

1. A statement that the study involves research, an explanation in lay terms the purpose of the research and the expected duration of the subject's participation, a detailed description of the procedures to be followed, and identification of any procedures which are experimental;
2. A full description of all reasonably foreseeable risks or discomforts to the subject;
3. A description of any direct benefit or lack thereof, or future possible benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. The following must be included: The New York Eye and Ear Infirmary (does) (does not) provide financial compensation for injury or illness resulting from participation in research. In case of physical injury resulting from participation in research. In case of physical injury resulting from your participation in the study, only immediate, essential, short-term treatment as determined by the doctors will be made available without charge to you. Payment for medical treatment, both standard and experimental, as well as treatment of any side effects will be assumed in the usual manner by me personally or through my medical insurance.

   When appropriate, one or more of the following elements of information shall also be provided to each subject:

   1. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
   2. Any additional costs to the subject may result from participation in the research
   3. The consequences of a subject's decision to withdraw from the research and

procedures for orderly termination of participation by the subject

4. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

5. The number of subjects involved in the study.

6. The Principal Investigator's contact information should the subject have questions about the study.

7. The statement: "For questions regarding your rights as a research subject, contact the Chairman of the IRB at 212-979-4447"

E. IRB ACTION

1. There will be a minimum of ten meetings per year or as often as the committee feels is needed. A new protocol must be presented at the scheduled meeting by the principal investigator, or if the IRB agrees before hand, a qualified co-investigator and discussion ensues. Any IRB member present at the meeting who is also the Principal Investigator, co-investigator or is involved in the protocol being voted on must abstain from the vote and will be listed as abstaining in the minutes. The chair will inform, in writing, the investigator of the committee's decision and any directions related to the protocol from the committee. All approval letters will list the approval period, which can be a maximum of one year.

2. All minutes of the meeting and discussions occurring in said IRB meeting are privileged information. No information from this meeting may be used by any members of the IRB committee for competing research or commercial purposes. If any member of the committee wishes to use materials presented at the IRB meeting outside the IRB, s/he must get permission in writing from the Principal Investigator.

3. Renewal Policy

The PI Is responsible for submitting to The IRB A Completed Continuing Review Form On The IRBMANAGER Web Site Before Expiration Of The IRB Approval Period For His/Her Protocol. Request For Renewal Or Termination Must Be Submitted By The Deadline For Submission Of Paperwork Prior To The Scheduled Meeting Date (Usually 10 Business Days Unless Otherwise Posted). As A Courtesy The IRB Will Send Reminders To The PI Alerting Of The Expiration Date Of IRB Approval By Email. The

PI Is Solely Responsible For Submitting A Report To The IRB With Renewal/Termination Request Well In Advance Of The Expiration Date.

For Protocols Where The PI Fails To Submit The Appropriate Continuing Review Form With For Request For Renewal Or Termination By The Expiration Date, The Protocol Must Be Considered Terminated. The IRB May Grant, Upon Request Of The Pi, An Extension Of The Approval Period Of Up To 2 Months. This Extension Allows For Patient Follow-Up Only And The Protocol Is Closed To New Enrollment As Of The Date Of Expiration. Once The Continuing Review Form Has Been Accepted By The IRB, The Committee Must Vote To Grant Renewal Or Terminate At The Next Scheduled Meeting. The Pi Shall Be Notified Of The Committee's Actions In Writing.

Protocols must be reviewed yearly, at a minimum, by the expiration date of the IRB approval period with a summary and appropriate data. If the IRB feels the protocol is such that the risk to the patient requires more frequent updates and renewals, the committee can determine specific procedures for such a protocol and the letter approving said protocol will include the approval period, if less than one year. As a courtesy, the IRB office will send a reminder of expiration of the approval period to the PI. All PIs will also have access to their protocol information, including approval periods, at all times via the IRBMANAGER web site which is accessible from any computer with internet access 24 hours a day, 7 days a week, using his/her username and password to gain access. As a further reminder, all approval letters to PI, regardless of action by the IRB, will have the protocol approval period listed. Expiration of the approval period of any protocol is the sole responsibility of the PI. Should the approval period lapse before the committee meets to vote on said protocol, the PI may request an extension of the approval period form the Chair until committee meets to vote on whether or not to approve renewal. The chair may grant up to 2 months of extension of the approval period for follow-up care only of the subjects already enrolled in study. The PI may not enroll new patients once the approval period has lapsed. The IRB will then vote at the scheduled meeting to approve or reject renewal. The PI shall be notified of IRB’s decision in writing.

4. It is incumbent upon the Principal Investigator to notify the IRB Chairperson immediately upon the recognition of any unusual side effects, unexpected findings and/or negative effects related to patient safety or function that occur related to an approved IRB protocol. This protocol will be revisited and reviewed with this additional information, at the next IRB Committee meeting.

5. Protocol termination submissions may be made by written notification to the IRB by the principal investigator only. Termination must include the reasons for termination and any summary of materials appropriate for said letter. This document will be kept on file.

6. The IRB must be notified, in writing, if additional Principal Investigator or co-investigators are added or deleted from an approved protocol

7. If an Investigator fails to submit a continuing review or annual report in a timely fashion or engages in scientific misconduct the IRB Committee has the right to suspend or terminate any and all protocols involving said investigator for just cause. A termination and/or suspension of PI and co-investigators will be communicated to the department chair, the President & CEO, the FDA and other appropriate government agencies.

   The PI of any active protocol, must inform the IRB of any FDA inspection and copy the IRB on any correspondence to or from the PI and the FDA or sponsor related to issues that include but are not limited to:

   Significant Deviations from Protocol
   SAE

F. FEES

Due to an increase in the regulatory demands placed on the IRB it was unanimously agreed upon at the July 13, 2004 meeting to establish a fee schedule for the processing of paperwork involved in clinical trials. This policy is applicable to research protocols funded by outside sponsors. Non-funded protocols may be exempt.

Initial protocol review: $1,250.00

Continuing protocol review: $250.00

IV. CONCLUSION

The New York Eye and Ear Infirmary has assumed an institutional responsibility to safeguard fully the rights and welfare of the individuals who are involved as human subjects in research. This document not only intends to accomplish this with as little interference as necessary with the progress of scientific research but also to communicate to our faculty a uniform ethical standard and practice for the conduct of research with human subjects. To this end, we are providing for collegial, community, and institutional review jointly with hospital affiliates.

APPENDICES

1. Instructions for preparing a research protocol
2. Instructions for preparing a consent form including suggested consent statements
3. Patient questionnaire to be included in consent form
4. HIPAA research authorization form
5. Instructions for HIPAA research authorization form
6. Financial disclosure form for research
7. List of IRB Members