

**REQUEST FOR PROJECT REVIEW  
BY THE  
INSTITUTIONAL REVIEW BOARD**

**TITLE OF PROJECT** \_\_\_\_\_

**PRINCIPAL INVESTIGATOR:** \_\_\_\_\_ **DEPT.** \_\_\_\_\_

**CO-INVESTIGATORS:** \_\_\_\_\_ **DEPT.** \_\_\_\_\_

\_\_\_\_\_ **DEPT.** \_\_\_\_\_

\_\_\_\_\_ **DEPT.** \_\_\_\_\_

**SOURCE OF FUNDING:** \_\_\_\_\_

**PUBLICATION RESTRAINTS** \_\_\_ YES \_\_\_ NO **IF YES, WHAT ARE THEY** \_\_\_\_\_

**TOTAL AMOUNT OF FUNDING:** \_\_\_\_\_ **IND** \_\_\_\_\_

**ESTIMATED TIME TO COMPLETE PROJECT:** \_\_\_\_\_

**DO YOU REQUEST AN EXEMPTION FROM IRB REVIEW?** \_\_\_ **IF SO, REASON (SEE IRB POLICY)** \_\_\_\_\_

**DO YOU REQUEST A WAIVER FROM OBTAINING INFORMED CONSENT?** \_\_\_\_\_

**IF SO, REASON (SEE IRB POLICY)** \_\_\_\_\_

**DO YOU REQUEST EXPEDITED REVIEW?** \_\_\_ **IF SO, REASON (SEE IRB POLICY)** \_\_\_\_\_

**I believe this project has scientific merit and adheres to the regulations of HHS and Mount Sinai Hospital Medical Center regarding investigations involving human subjects.**

\_\_\_\_\_  
**Principal Investigator** \_\_\_\_\_ **Date** \_\_\_\_\_ **Dept. Chairman** \_\_\_\_\_

\_\_\_\_\_  
**Co-Investigator** \_\_\_\_\_ **Date** \_\_\_\_\_ **Dept. Chairman** \_\_\_\_\_

\_\_\_\_\_  
**Co-Investigator** \_\_\_\_\_ **Date** \_\_\_\_\_ **Dept. Chairman** \_\_\_\_\_

**MOUNT SINAI HOSPITAL MEDICAL CENTER OF CHICAGO**

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**IRB DATE RECEIVED:**

**DATE SENT TO RESEARCH COMMITTEE:**

**DATE OF ACTION:**

**ACTION:**

**ANNUAL REVIEWS:**

LMA:sg  
10/15/97 (Revised)

**MOUNT SINAI HOSPITAL MEDICAL CENTER OF CHICAGO  
GUIDELINES FOR APPLICATIONS FOR PROJECT APPROVAL BY  
INSTITUTIONAL REVIEW BOARD**

**Attach 15 copies of the protocol and informed consent.** The protocol must outline the aim, the plan of attack and the possible significance of the proposed activity in sufficient detail for members of the Institution Review Board to perceive the character and scope of the investigation and to enable the Institutional Review Board to evaluate the role of human subjects in the study, the risks involved for them and the potential medic benefits to be derived by them and/or by others from the investigation.

Include:

1. Approximate **number of subjects** to be used in the study.
2. **Drugs to be used**; their pharmacology and toxicity; for unapproved (**FDA**) drugs this should be discussed in detail.
3. **Experience gained** in animal studies and preliminary studies in humans should be summarized and literature references and own publications on the subject cited.
4. Procedures to be carried out.
5. **Method to be used** to secure informed consent of human subjects or their authorized representatives and manner in which their rights will be protected. Enclosed sample form that will be used (*see the attached outline approved by the IRB*). Clearly indicate a number corresponding to "**General Requirements for Informed Consent**" where each item is included in the informed consent. The investigator will give all explanations on the form in understandable language. Any modification of the Informed Consent must be individually and specifically documented and approved by the IRB.
6. Relevant **bibliography**.

The IRB shall approve research based on the IRB's determinations that the following requirements are satisfactory:

1. Risks to subjects are minimized:
  - a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
  - b. Whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance, of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research

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*(as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).* The IRB shall not consider long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by **§45 CFR 46.116 and 46 CFR 50.25**.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by **§45 CFR 46.117 and 46 CFR 50.27**.
6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. All research involving **HIV testing** shall be performed in accordance with the IRB protocol, **"Informing Research Subjects of HIV Test Results."**
9. Children involved as subjects in research shall receive the additional protection provided under **§45 CFR 46 Subpart D**, which may include solicitation of their assent to participate in the research.

**MOUNT SINAI HOSPITAL MEDICAL CENTER OF CHICAGO  
POLICY OF THE INSTITUTIONAL REVIEW BOARD**

1. All investigational devices and drugs used in the **Mount Sinai Hospital Medical Center** must comply in all aspects with this policy as well as the policies outlined in the **Assurance of Compliance with HHS Regulations for Protection of Human Research Subject**.
2. **Emergency use of a drug or device requiring IRB approval** may be used once with consent of the department chairman, **provided the Chairman of the IRB is notified within 5 days** of its use and a protocol and informed consent (*if applicable*) is submitted. No further use is allowed without the permission of the IRB or his designate is required.
3. In emergency situations exemption from obtaining informed consent for **FDA** regulated devices is permitted if the following criteria are met:

***§50.23 EXCEPTION FROM GENERAL REQUIREMENTS***

- a. The obtaining of informed consent shall be deemed feasible unless, before use of the test article (*except as provided in paragraph (b) of this section*), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:
  1. The human subject is confronted by a life-threatening situation necessitating the use of the test article.
  2. Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
  3. Time is not sufficient to obtain consent from the subject's legal representative.
  4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

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**POLICY OF THE INSTITUTIONAL REVIEW BOARD**

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- b. If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph **(a)** of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, **within 5 working days after the use of the article**, reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.
- c. The documentation required in paragraph **(a) or (b)** of this section shall be submitted to the IRB **within 5 working days after the use of the test article**.
4. Normally on-going review is done on a yearly basis, however, the majority of members of the IRB at any meeting may request a more frequent review if there are concerns over unusual risks. Any member may request independent verification of no material changes at any time if they have reason to suspect changes. At the time of each review a copy of the current consent form must be submitted for review.
5. All research involving radioactivity on subjects less than 18 years old will be reviewed by the Radiatic Safety Committee and a recommendation made to the IRB before final action.
6. Investigators must notify the IRB of any deviation from the investigational plan. In case of an emergency, to protect the life or physical well being of a subject, the investigator shall notify the Chairman of the IRB within 48 hours.
7. All records will be maintained for a minimum of 3 years following completion of a study.
8. The IRB will report to the **President of the Medical Center**, the **Food and Drug Administration**, and/or the **Office of Protection from Research Risks (HHS)** any serious or continuing non-compliance by investigators with the requirements and determinations of the IRB.
9. Applications for IRB review as well as IRB policies and procedures may be obtained from the **IRB Staff Secretary or the office of the Chief Operating Officer**.

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**POLICY OF THE INSTITUTIONAL REVIEW BOARD**  
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10. For IRB review of a project, the principle investigator must complete the application for IRB review (*appended*) and supply the additional information, including an informed consent marked to indicate a required items required on the instructions attached to the application and return is to the IRB staff secretary. The IRB secretary will notify the chairman of its receipt; the chairman will review the application; determine if it is exempt (*see Assurance of Compliance*) or requires full review by the IRB. If eligible for exemption the Chairman will review the project; and if found not to be exempt the project will be processed for expedited and/or full review. If the Chairman believes the project is eligible for expedited review he/she will grant this; send a copy of the application, protocol and informed consent to all members of the IRB and at the next scheduled meeting of the IRB ask if anyone on the Committee requests a full review (*see Assurance of Compliance*). If the Chairman does not feel a project is eligible for expedited review it will be scheduled for full review at the next regular IRB meeting. All review is conducted as outlined in "*A. IRB Responsibilities*" of the Assurance of Compliance Plan.
11. All approval letters will inform the investigator of need to promptly report to the IRB unanticipated problems involving risks to subject or others changes in the research activity, and not to initiate any changes in IRB approved research without further IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects.
12. All research involving **HIV testing** shall be performed in accordance with the IRB protocol, "*Informing Research Subjects of HIV Test Results.*"
13. Children involved as subjects in research shall received the additional protection provided under **§45 CFR 46 Subpart D**, which may include solicitation of their assent to participate in the research.

LMA:sg  
Revised 10/15/97

**MOUNT SINAI HOSPITAL MEDICAL CENTER  
INSTITUTIONAL REVIEW BOARD  
PROCEDURES FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS**

An Institutional Review Board (**IRB**) is established and its **Rules and Regulations** are adopted according to **§ 45 CFR Part 46 Assurance of Compliance with HHS Regulations for the Protection of Human Research Subjects** and is effective on **June 18, 1991**, for all research, except that which has been approved on a prior date. All research with prior date approval will comply with these procedures by September 18, 1991. Rules and Regulations outlined in **"§ 46 CFR Part 9 of Protection of Human Subjects; Informed Consent; Standards for Institutional Review Boards for Clinical Investigations; and Clinical Investigation which may be revised through Expedited Review procedure"** are also complied with.

All research submitted to the IRB for consideration and approval must be in the format, **"Application for Project Approval by the Institutional Review Board (IRB)" revised date 10/15/97.**

Any drug used in the research and classified as investigational must be placed in the **'Drug and Therapeutic Committee's Investigational Drug Information Registry," dated 6/1/81.**

The copy of the informed consent submitted with the application must follow the outline, **"General Requirements for Informed Consent," revised date 10/15/97.** It will be the responsibility of the investigator to include all elements of the consent in the sample.

The Committee must receive projects for review at least **10 days before** a meeting. Projects should not be added to the agenda if they are received within one week of a scheduled meeting.

***During the research, if contraindications, warnings, precautions, adverse reactions, doses and/or technique of administration of the drug change, the investigator should notify the Pharmacy so the information sheet to the nurses can be changed accordingly, and also, if the adverse reaction is serious or a death occurs, the investigator must report this immediately to the Chairman of IRB for review by the IRB. This information must be contained in the final progress report after completion of the study. Inactivation and termination of a study must be reported to the Pharmacy and the Chairman of the IRB***

**Only the principal investigator or co-investigator is authorized to obtain an informed consent from the patient.**

The original signed informed consent shall be included in the subjects permanent hospital record and handled by the medical records department according to hospital policy for preservation of patient medical records. A copy of the informed consent shall be given to each participating subject and a copy of each signed informed consent shall be sent to the IRB secretary. It is the responsibility of the principle investigator to carry out this provision.

Verification of compliance will be done by monitoring projects on a random basis. Records will be checked to see that copies of informed consents on all subjects have been submitted to the IRB and have been properly

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*Procedures for the Protection of*  
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Members of the IRB shall review ongoing projects each year with some of the principle investigators to assure compliance ***(as assigned by the Chairman)***.

Any member of the IRB who learns of any information that would suggest any project is not in full compliance should promptly notify the Chairman who is obligated to investigate the matter and make a report to the IRB at a regular meeting.

Annual progress reports on all projects are required. Included in this report should be any changes in the outlined procedure, the number of patients studied, any adverse reactions and the estimated time to complete the study.

New information given to subjects and a copy of the currently used informed consent form must be submitted. At the time of initial approval and at each annual review, the IRB by majority vote of the members present, may require more frequent monitoring if any concerns are expressed particularly over potential or real adverse reactions or risks.

***“Whenever a research project(s) is subject to an outside audit, the results of such an audit must be filed with IRB within 10 days upon receipt of the results (preliminary/final). Verbal reports will be reduced to writing immediately and must follow the same standard”, dated 11/8/95.***

***The IRB Approved Standard Withdrawal Form should be used by all investigators when a patient request to withdraw or be terminated from a study, Revised date 7/25/95.***

Applications for IRB review can be obtained from the IRB Secretary or Chairman. Requests for IRB review should be completed and forwarded according to the instructions provided with the ***“IRB Application for Review.”*** Applications not completed in accordance with instructions will be returned to the investigator and not considered until complete in all aspects. Requests for exemption from IRB approval will be reviewed by the Chairman of the IRB. The investigator will be notified of IRB Chairman decision. If exemption is granted, no further review is required; if exemption is not granted then the usual procedures must be followed ***(Criteria for exemption from IRB review are appended)***.

***Members of the Institutional Review Board are appointed by the President of the Medical Center.***

***These procedures supersede the procedures issued on November 8, 1995.***

LMA:sg  
*Revised 10/15/97*

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GENERAL REQUIREMENTS FOR INFORMED CONSENT**

Title of study \_\_\_\_\_ (1) \_\_\_\_\_ (2) A statement that the study involves research, (3) an explanation of the purposes of the research and (4) the expected duration of the subject's participation, (5) a description of the procedures to be followed, and (6) identification of any procedures which are experimental; (7) A description of any reasonably foreseeable risks or discomforts to the subject; (8) A description of any benefits to the subject or to others which may reasonably be expected from the research; (9) A disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject; (10) A statement describing the extent, if any to which confidentiality of records identifying the subject will be maintained; and notes the possibility that the Food and Drug Administration may inspect the records. (11) The statement, *"I understand that in the event of physical injury resulting from this research, there is no compensation available from the medical center or investigator for such injury and that I will obtain any necessary medical care for such injury in the same manner in which I obtain any other medical care"*

(12a) An explanation of whom to contact for answers to pertinent questions about the research and (12b) research subjects, rights, the statement, *"If I have any questions concerning my rights as a research subject, while on this study, I will contact Mr. Kenneth Richmond, Senior Vice-President and Chief Operating Officer at (773) 257-6435"* and (13) whom to contact in the event of research-related injury to the subject; and (14) A statement that participation is voluntary, (15) refusal to participate will involve no penalty or loss of benefits to which

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**GENERAL REQUIREMENTS FOR INFORMED CONSENT**  
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the subject is otherwise entitled, and **(16)** the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled, and a statement that **(17)** a withdrawal request form will be given to him/her for their signature. *When appropriate, (18) thru (26), one or more of the following elements of information shall also be provided to each subject:* **(18)** A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable **(19)** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; **(20)** Any additional costs to the subject that may result from participation in the research;

**(21)** The consequences of the subject's decision to withdraw from the research and **(22)** procedures for orderly termination of participation by the subject; **(23)** A statement that significant new findings developed during the course of the research which may related to the subject's willingness to continue participation will be provided to the subject; and **(24)** The approximate number of subjects involve in the study. **(25)** A statement that provision will be made for soliciting the assent of children who are involve in research, when in the judgment of the IRB the children are capable of providing assent, and that this assent shall be sought in addition to solicitation of parental permission. **(26)** A statement regarding research involving HIV testing, disclosing whether identifiers will be recorded and if identifiers will be recorded, a

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statement as to whether they will be recorded separately from the other data, with linkage restored only when necessary to conduct the research. Further, the statement shall disclose who will be entitled to see records containing identifiers, taking into account the possibility of review by a funding agency on the FDA, if applicable. All consents will end with the following format: **(27)** The statement, ***"I am willing to participate in a study described above to be conducted by \_\_\_\_\_(28)\_\_\_\_\_ at the Mount Sinai Hospital Medical Center, 2755 West 15th Street, Chicago, Illinois 60608"***

\_\_\_\_\_**(29)**\_\_\_\_\_  
Signature of the subject  
or subject's legal  
representative.

\_\_\_\_\_**(30)**\_\_\_\_\_  
Signature of witness

\_\_\_\_\_**(31)**\_\_\_\_\_  
Printed name of person  
whose signature appears  
above

\_\_\_\_\_**(32)**\_\_\_\_\_  
Printed name of witness

\_\_\_\_\_**(33)**\_\_\_\_\_  
Signature of Investigator  
explaining consent

\_\_\_\_\_**(34)**\_\_\_\_\_  
Address of witness

\_\_\_\_\_**(35)**\_\_\_\_\_  
Date

***(Numbers 36, 37 and 38 must be signed only if patient cannot read consent and needs an interpreter)***

\_\_\_\_\_**(36)**\_\_\_\_\_  
Printed name of Interpreter

\_\_\_\_\_**(37)**\_\_\_\_\_  
Signature of Interpreter

\_\_\_\_\_**(38)**\_\_\_\_\_  
Address of Interpreter

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