THE NEBRASKA METHODIST HOSPITAL 8303 DODGE STREET OMAHA, NEBRASKA 68114 402-354-4000

Institutional Review Board
Request for Review
Of Investigational Study

Use of Form: This form is to be used by the principal investigator to request initial review and approval of a proposed study involving human subjects. This form should not be used for annual or other periodic status reports of previously approved studies, unless approval for a modification is requested. For Medical Research this form must be completed, with attachments, and submitted to the IRB Manager in the Mecial Staff office. For nursing and allied health research, complete with attachments, print, and give to the Chair fo the Nursing Research Council.

1. **Title of Study:**

2. **Date of this Request:**

3. **Medical Staff Department:**

4. **Principal Investigator's Name:**
   Office Address:
   Office Phone:

5. **Secondary Investigator(s):**

6. **Sponsor/Manufacturer Name:**
   Address:
   Contact Person:
   Telephone:

7. **Reason for Request (Check All Which Apply):**
   - ☐ Federally Sponsored Human Research
   - ☐ Investigational Drug Under FDA Supervision
   - ☐ Investigational Device Under FDA Supervision
   - ☐ Other (Explain):
   - ☐ Intraocular Lens Classified Investigational by FDA
   - ☐ IRB Review Required by Sponsor/Manufacturer
   - ☐ Modification of Previously Approved Study

   _____

8. **Study Will Be Conducted:**
   - ☐ Wholly or Partially at Methodist Hospital
   - ☐ Entirely Off Methodist Hospital Campus

9. **Check All Special/Vulnerable Groups Within Subject Population:**

☐ Children (Ages: _____)	☐ Physically Disabled
☐ Pregnant Women	☐ Mentally/Emotionally Disabled
☐ Fetuses	☐ Other (Describe:

Please provide summary statements addressing the following points. Although this information may be contained in the other documents you submit, your summaries here will help assure prompt and informed IRB action. If you are seeking only to modify a previously approved study, you may simply describe the changes (or "no change") in each category.

10. **Nature and Purpose of the Study:**

11. **Characteristics of Subject Population** (Number, Age Ranges, Gender, Ethnic Background, and Health Status; Criteria for Inclusion and Exclusion, and Justification for the Utilization of Any Special/Vulnerable Groups):

12. **Method of Subject Selection** (Methods to be Employed in the Identification/Recruitment of Potential Subjects):

13. **Risks to the Subjects** (Potential Risks; Probability, Severity, Potential Duration and Reversibility of Such Risks):

14. **Protection Against Risks** (Procedures to be Utilized to Prevent/Minimize Any Potential Risks):

15. **Benefits** (Potential Benefits To Be Gained By the Subject as Well as Benefits That May Accrue to Medical Science or Society in General):

16. **Risk-Benefit Analysis** (Why the Risks to the Subject are Reasonable in Relation to the Anticipated benefits to the Subject and/or in Relation to the Importance of the Knowledge that May Reasonably be Expected to Result):
See above.

17. **Therapeutic Alternatives** (Therapeutic Alternatives That May Be Advantageous to the Subject):

18. **Informed Consent:** Please describe the process by which you will obtain the informed consent of each study subject, addressing (i) who conducts the main consent discussion with the subject, (ii) when this discussion takes place, (iii) who is present at this discussion and what materials are presented to the subject, (iv) when the subject is asked to sign the consent document, (v) whether the subject is provided a copy of the consent document, (vi) whether you anticipate ever enrolling a subject with surrogate consent because the subject is not competent to consent for himself or herself, and (vii) any circumstances under which you might enroll a subject without informed consent.

19. **Documentation:** The following documents are submitted with this Request for Review (If No, explain why not and where/when the document(s) will be available):

○ Yes	◉ No	Complete Investigational Plan and Protocol
○ Yes	○ No	Report of Prior Investigations
○ Yes	○ No	Patient Informed Consent Form
○ Yes	○ No	Reporting Forms That the Sponsor Requires from IRB
○ Yes	○ No	Medical Staff Department Recommendation
		○ Yes ○ No (Secondary Investigations): Certification of Review and Approval by the Primary IRB
○ Yes	○ No	Fee **** (see page 4)
◉ Yes	◉ No	Other (Describe):

20. **Financial Considerations:**
    a. Do you or any other local investigators have any financial or management interest in the sponsor or manufacturer, direct or indirect, in any form? ○ No ○ Yes, as Follows:

    b. Will there be any payments from the study sponsor, study group or other interested party to you, your staff or your institution in connection with this study, whether designated for fees, expenses, or otherwise?

    ○ No ○ Yes As Follows (Please provide an itemization of all anticipated payments, and how they will be used or applied. A study budget should be provided if available):

    c. Will there be any costs or charges to the patients in this study, beyond what they would incur from standard or alternative therapies? ○ No ○ Yes, as Follows (Including Expected Source of Payment):

21. **Research/Investigator Status:**

    a. Has the proposed study, or any substantially similar study, previously been denied approval or had its approval suspended or revoked by this IRB or any other IRB? ○ No ○ Yes (explain):

b. Have you (or to the best of your knowledge, any secondary investigator) ever been subject to any of the following (or is any formal investigation or other formal action pending which could lead to such a result):

- Revocation of approval to serve as an investigator in a research study, imposed by any IRB, sponsor or other entity? ◯ No ◯ Yes (explain):

- Debarment as a government contractor, or disqualification from any government or private grants or research programs? ◯ No ◯ Yes (explain):

- Criminal prosecution or civil lawsuit seeking criminal penalties, injunction or damages arising out of clinical research involving human subjects? ◯ No ◯ Yes (explain):

c. Do you agree to notify the IRB chair if events occur which would change any of your answers to the preceding questions? ◯ No ◯ Yes

d. Have you received, and do you agree to review, understand and be bound by, this IRB Handbook? ◯ No ◯ Yes

Investigator's Certification: I certify that the foregoing is complete and accurate to the best of my knowledge. I will advise the Chair of the IRB of any significant changes of which I become aware. I have received, read and understand the Handbook for IRB Members and Investigators, including the Statement of Ethical Principles and Policy, and agree to comply with all of the terms, conditions and standards contained within the Handbook, with all periodic reporting requirements, and with all applicable laws and regulations.

Signature of Principal Investigator: _____

Date Submitted:

A typed name in the above Signature of Principal Investigator box constitutes a signature of the principal investigator for this study.

****Please note: The Methodist Hospital IRB Guidelines require a one-time fee of $2000.00 for submission of new protocols. This fee applies to industry-sponsored studies, not nonprofit cooperative research group trials or local physician-investigators. The fee is due upon submission of the Request for Review.

Submit