

**METHODIST HEALTHCARE  
INSTITUTIONAL REVIEW BOARD**

**Project Review Form \_\_\_\_\_ / Closure Form \_\_\_\_\_**

(Please check appropriate box)

MHIRB #

Review Cycle: \_\_\_\_\_ months

Study Title:

Principal Investigator:

Phone Number:

Mailing Address

Original MHIRB Approval Date:

Last Approval Date:

To ensure the protection of the rights and welfare of human research subjects, the Methodist Healthcare Institutional Review Board (MHIRB) is responsible for conducting a review of active research projects. Responses submitted on this form will provide the basis for continued approval of your project. Additional information may be required.

For project review, this report should be submitted to the MHIRB Administration by \_\_\_\_\_ for consideration at the \_\_\_\_\_ MHIRB meeting. MHIRB approval expires \_\_\_\_\_. Thereafter, study-related procedures must cease, and can only be resumed after approval of a new submission.

**PROJECT STATUS**

1. This project is

- Active and open to enrollment
- Active, but closed to enrollment as of (date): \_\_\_\_\_
- Active, closed to enrollment and data analysis ONLY
- Active, but enrollment is on hold as of (date: \_\_\_\_\_  
Reason: \_\_\_\_\_)
- Closed on (date): \_\_\_\_\_  
Reason for termination: \_\_\_\_\_)

2. Date study initiated at MH: \_\_\_\_\_

3. Date of last monitor/auditor visit: \_\_\_\_\_  
Name of last monitor/auditor (indicate company or monitor name rather than individual's name)

Summarize findings:

**Subject Profile**

1. **Total** number of subjects enrolled at MH: \_\_\_\_\_  
Number of subjects signing ICF \_\_\_\_\_

Number of subjects active \_\_\_\_\_  
 Number of subjects completing study \_\_\_\_\_  
 Number of subjects withdrawn \_\_\_\_\_  
     Dissatisfaction: \_\_\_\_\_  
     Relocation: \_\_\_\_\_  
     Due to adverse event: \_\_\_\_\_  
     WD by PI or sponsor: \_\_\_\_\_  
     Other reason: \_\_\_\_\_  
     Describe other reason: \_\_\_\_\_  
 Number of subjects lost to follow-up \_\_\_\_\_  
 Total number of subjects enrolled  
 at MH since last review \_\_\_\_\_

2. Demographics of subjects enrolled at MH:

Characteristic	Number
Male	
Female	
African-American	
White (nonLatino)	
Asian or Pacific Islander	
Native American	
Hispanic/Latinto	
Other	

3. Have all subjects signed informed consent forms?

- YES  
 NO (explain \_\_\_\_\_)

Where are copies of signed informed consent forms maintained? \_\_\_\_\_

**Must attach copies of the first and last SIGNED informed consents.**

4. Did you experience any unanticipated difficulty recruiting or retaining subjects for this study?

- YES (explain \_\_\_\_\_)  
 NO

5. Did you receive any complaints about this study?

- YES (explain \_\_\_\_\_)  
 NO

**RISK/BENEFITS**

- 1. Are actual risks/benefits similar to those anticipated?  
 YES  
 NO  
Explanation: \_\_\_\_\_
  
- 2. Have new risks/side effects been identified by you or the sponsor since last review?  
 YES  
Explanation: \_\_\_\_\_  
 NO
  
- 2. Do the benefits derived from this study outweigh the risks to the subject?  
 YES  
 NO  
Explanation: \_\_\_\_\_
  
- 3. Have the procedures used in this project now become standard and recognized procedures that have diagnostic, therapeutic, or prognostic value?  
 YES  
 NO
  
- 4. What risks/benefits have changed since the last review?

**Current Risk Determination:**

- 1. The research may result in possible harm/distress/loss in which area(s) of the subject's life? (check all that apply)  
 (0) None  
 (1) Psychological  
 (1) Physical  
 (1) Social  
 (1) Economic
  
- 2. Is there a possibility of the subject being identified from participating in the study?  
 (0) No     (1) Yes
  
- 3. The likelihood of the subject developing toxicities/complications from the study intervention is: (check one)  
 (0) None  
 (1) Possible but not likely and no greater risk than in routine testing and care.  
 (2) Probable with a greater risk than in routine testing and care.  
 (3) Definite with a greater risk than in routine testing and care.

**OTHER REQUIRED INFORMATION (attach additional pages if necessary):**

1. Summarize outcomes/findings/observations of the study to this date. Include how many subjects had desired outcome, how many, failed therapy. Attach any interim reports received from the sponsor or reports generated by the MH investigators.
  
2. List any adverse events and their relationship to the test article not previously reported.
  
3. Summarize all adverse events, including local and at other sites.
  
4. List any new information about the test article since the last MHIRB review.
  
5. Does this research utilize an investigational drug or device?  
 YES      IND/IDE# \_\_\_\_\_  
 NO
  
6. Has the investigational drug or device received FDA approval?  
 YES      Date \_\_\_\_\_  
 NO

**REQUIRED ATTACHMENTS:**

1. Copy of the current consent form with MHIRB date stamp (if enrollment is ongoing).
2. Copies of the first and last signed informed consent documents for this study.
3. List of all enrolled research subjects who have signed informed consent forms for this project. List must include the (1) research subject's name, (2) medical record number (inpatients only), (3) date of birth, (4) date consent form was signed, and (4) name of person who obtained the consent from the subject.

**The attached informed consent log must be utilized to provide this information. This information is required for all reapprovals AND closures.**

Your signature below indicates that you accept responsibility and have followed the ethical guidelines as set forth by the Methodist Healthcare IRB in conducting the research described. Further, your signature below indicates that the information provided is accurate and complete to the best of your knowledge.

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Signature of Principal Investigator

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Date

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Signature of Co-Principal Investigator

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Date

Please return this form (with attachments) to:

Methodist Healthcare  
Institutional Review Board Administration  
1325 Eastmoreland Suite 374  
Memphis, TN 38104

Date mailed: 10/03/2007

Mailed to: