

Request for IRB Review and Approval

Request for:

- (1) Full board review of protocol and consent ___
- (2) Exemption from review ___
- (3) Expedited review ___
- (4) Waiver of consent or consent documentation ___

Study Title: _____

Study Sponsor: _____

Name of Contact Person: _____

Address: _____

Phone Number: (_____) _____

1. **A copy of the entire study must accompany this request, including a copy of the consent form as it is to be used at DCMH.**

2. **Does this study involve use of a device?** Yes__ No__

Is the device FDA-approved or cleared for marketing and use? Yes__ No__

Is that approval/clearance for the same use as the use in this study? Yes__ No__

What is the IDE Number? _____

If there is no IDE Number, please explain _____

Is the potential risk to subjects significant? Yes__ No__

3. **Does this study involve use of a drug?** Yes__ No__

Is the drug FDA-approved for marketing and use? Yes__ No__

Is this approval for the same use as the use in the study? Yes__ No__

What is the IND Number? _____

If there is no IND number, please explain: _____

Has the Investigator's Brochure been submitted? Yes__ No__

Has a copy of the study and consent form been forwarded to the DCMH inpatient Pharmacy? Yes__ No__

4. **Is a study summary attached?** Yes__ No__

NOTE: The summary should address the following information in lay terms, and should ordinarily be one to two pages in length.

- Rationale for study, including a summary of previous relevant research
- Design and procedures for the current study
- Characteristics of study population, including recruitment procedures and identification of any vulnerable subject populations
- Potential benefits for participants
- Most significant risks for participants, including any deception

- Expected duration of each subject's participation
- Reimbursement of subjects for participation, treatment costs, and/or injuries (describe amount and nature of reimbursement if applicable)

6. **How many participants do you expect to accrue from DCMH?** _____
 Will all patients who meet eligibility criteria be offered the opportunity to participate in this study? Yes__ No__
 If not, explain: _____

7. **Do you expect to enroll any subjects from one of the following potentially vulnerable groups?** (check all applicable)
 Children Yes__ No__
 Prisoners Yes__ No__
 Pregnant Women Yes__ No__
 Mentally Disabled Yes__ No__
 Economically Disadvantaged Yes__ No__
 Educationally Disadvantaged Yes__ No__
 If yes, what additional safeguards have been instituted to protect their welfare?

8. **Does the consent form contain an adequate description of provisions for protecting the privacy of subjects?** Yes__ No__
 If no, explain: _____

9. **Is study oversight and monitoring internal__ or external__?**
 Describe study oversight _____

10. **Does this study require any special procedures in any Hospital Department (including but not limited to Radiology, Laboratory, Pharmacy, Nursing, and/or Finance?** Yes__ No__
 If so, describe: _____

11. **Do you have any financial relationship with the study sponsor that could constitute a conflict of interest (proprietary interest, stocks, prompt recruitment bonuses etc.)** Yes__ No__
 If so, describe: _____

12. **Is there any compensation to the Investigator or the Institution for participation in this study?** Yes__ No__
 If so, describe: _____

13. Do you agree to fulfill the responsibilities of an Investigator as described in the DCMH Guidelines for the Clinical Investigator, and in compliance with applicable federal, state, and local laws?

Yes__ No__

Name of Investigator (Print)

Signature of Investigator

Date

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FOR IRB USE ONLY

Study Number and/or Title: _____

The IRB reviewed the above study and related materials on _____. Based on this review, the following action has been taken:

- The study and consent were approved as submitted____
- The study and consent were approved pending receipt and approval of recommended revisions (details attached) ____

The study approval is for a period of ____ months. An update of the progress of this study must be received by the IRB Coordinator by _____ so that study review and reapproval can take place before the current approval expires.

The study and consent will be reviewed again by the IRB pending receipt of recommended revisions (details attached) ____
The study has been disapproved (details attached) ____

Signature of IRB Chairman

Date