

THE LANCASTER GENERAL HOSPITAL
APPLICATION FOR RESEARCH PROJECT

APPLICATIONS WHICH ARE INCOMPLETE OR HAVE MISSING SIGNATURES WILL BE RETURNED AND MAY DELAY APPROVAL BY THE INSTITUTIONAL REVIEW BOARD. INSTITUTIONAL REVIEW BOARD MEETINGS ARE HELD THE SECOND TUESDAY OF THE MONTH. APPLICATIONS MUST BE RECEIVED AT LEAST TWO WEEKS PRIOR TO THE SCHEDULED MEETING.

IS THIS PROJECT SUBMITTED FOR CONSIDERATION UNDER THE "COOPERATIVE AGREEMENT" BETWEEN LGH & LRMC? NO [] YES [] If YES, HAS LRMC RECEIVED COPIES OF ALL DOCUMENTS? NO [] YES []

1. DATE OF APPLICATION:
2. TITLE OF PROJECT:
3. PRINCIPAL INVESTIGATOR:
4. COLLABORATORS:
5. SPONSOR:
6. BRIEF SUMMARY AND OBJECTIVE OF THE PROJECT
7. ESTIMATED DURATION OF THE PROJECT:
8. ESTIMATED NUMBER OF SUBJECTS TO BE ENROLLED: LGH site _____ Total _____
9. WILL THIS PROPOSED DRUG/DEVICE/PROCEDURE REPLACE AN EXISTING DRUG/DEVICE/PROCEDURE? NO [] YES [] (IF YES, ESTIMATE ANY EXPECTED COST INCREASE OR SAVINGS)
10. ARE THERE OTHER SIMILAR DEVICES/DRUGS/PROCEDURES (IN USE OR INVESTIGATIONAL)? NO [] YES [] (IF YES, ITEMIZE)

11. **WILL THIS PROJECT REQUIRE HOSPITAL RESOURCES (PERSONNEL, SPACE, EQUIPMENT, OR SERVICES)? NO [] YES [] (IF YES, ITEMIZE AND ATTACH)**
12. **WHAT IS THE EXPERIMENTAL STATUS OF THE DRUGS AND DEVICES USED IN THE STUDY? LIST THE FDA NUMBER FOR DEVICES AND INDICATE WHETHER THE DEVICE IS APPROVED, INVESTIGATIONAL OR EXPERIMENTAL.**

DRUG OR DEVICE	APPROVED? (POST-MARKETING)	INVESTIGATIONAL? (REIMBURSIBLE)	EXPERIMENTAL? (NON-REIMBURSABLE)	FDA NUMBER? (DEVICES ONLY)

13. **LIST ANY OTHER LGH DEPARTMENT INVOLVED IN THE PROJECT. SIGNATURES OF DEPARTMENT CHAIRS AND DEPARTMENT MANAGER/DIRECTOR ARE REQUIRED.**

DEPARTMENT	CHAIRMAN (SIGNATURE)	MGR/DIRECTOR (SIGNATURE)

14. **AS AN APPLICANT, I HAVE READ "RESEARCH PROJECT PROCEDURE" (HOSPITAL POLICY NO. 5003) AND I AGREE TO ABIDE BY IT. IN ADDITION, I UNDERSTAND THAT I MUST OBTAIN SUBJECT AUTHORIZATION AS REQUIRED UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) PRIVACY REGULATIONS, UNLESS I SPECIFICALLY REQUEST A WAIVER OF AUTHORIZATION AND PROVIDE JUSTIFICATION ALONG WITH THE "WAIVER OF HIPAA AUTHORIZATION" FORM TO THE IRB AS PART OF THIS APPLICATION PROCESS.**

SIGNATURE OF APPLICANT

15. **APPROVED BY DIVISION CHIEF (MANAGER) AND DEPARTMENT CHAIRMAN (DEPARTMENT DIRECTOR) (SIGNATURES REQUIRED):**

DIVISION CHIEF/ MANAGER

DEPARTMENT CHAIR/DEPARTMENT DIRECTOR

16. **ATTACH FOUR COPIES OF THE ENTIRE PROTOCOL, INVESTIGATOR'S BROCHURE, AND 19 COPIES OF THE INFORMED CONSENT FORM, HIPAA AUTHORIZATION, AND OTHER FORMS YOU MAY BE SUBMITTING PREPARED OR REVISED USING THE INSTITUTIONAL REVIEW BOARD'S "CRITERIA FOR RESEARCH PROTOCOLS" AND THE "CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY" TEMPLATE. IF YOU ARE REQUESTING EXPEDITED REVIEW OF THE PROTOCOL, ATTACH TWO COPIES OF THE ENTIRE PROTOCOL AND ANY OTHER FORMS YOU MAY BE SUBMITTING.**

APPROVAL PROCESS

Institutional Review Board:

DATE

Revised 01/30/09