

**APPLICATION FOR IRB APPROVAL OF RETROSPECTIVE STUDIES
(NOT FOR POSTGRADUATE THESIS OR MEDICAL STUDENT OR ALLIED HEALTH OR NURSING
STUDENT PROJECT RELATED)**

CHRISTIAN MEDICAL COLLEGE, VELLORE

1. Title of Research Project: Attributable cost of a nosocomial infection in the intensive care unit

2. Acronym, if any:

3. Name and Designation of Principal Investigator (s) / Co investigator(s) / Co - author (s) Dr Binila Chacko

Address for communication (including telephone and fax numbers and email id, employment number):

Division of Critical Care
Christian Medical College
Vellore 632004

If Post Graduate Registrar:

Enrollment date of PG Course: mm/yyyy

Completion date of PG Course: mm/yyyy

Contact person for scientific queries if different from Principal investigator
(Including telephone and fax numbers and email id, employment number):

4. Source/s of Monetary or Material Support

Internal Fluid Research Grant : NIL

External : NIL

Departmental fund : NIL

5. Contributions of each of the author/investigators(s):

Dr Binila Chacko -Conception, data collection, data entry, literature search, write up

Dr JV Peter - Conception,literature search, statistical analysis, write up

Dr Hema Paul-Data collection, data entry, literature search, write up

Dr Kurien Thomas-Costing aspects, analysis and write up

Dr Thambu David-Costing aspects, write up

Dr Sowmya Sathyendra-Write up

6. Sites of the study (including departments where the study was done): Medical ICU and HDU

7. Brief Summary (in 250 words): Intensive Care Units (ICUs) in developing countries are facing a rising burden of increasing cost of care. Although several studies from developed countries have demonstrated that nosocomial infections increase cost and worsen outcome, there is limited costing data from developing countries on nosocomial infections acquired during intensive care unit (ICU) admission. We aim to determine the attributable cost and mortality of a nosocomial infection in the intensive care unit. Adult patients (>18 years) admitted to a 24-bed medical critical care unit in India over 1-year period were included in the study. Only infections occurring during ICU stay will be included. Treatment cost and outcome data has already been collected during a prospective study on ICU cost. (IRB Min 7283 dated 22.9.2010). This data will be merged with nosocomial infection data collected prospectively by the hospital infection control committee. We will be looking at the overall attributable cost of a nosocomial infection and the factors contributing to the same. Each infection's contribution to the attributable cost will also be looked into .

8. Provide the date range of the chart review: (if this is a retrospective chart review, the end date should antedate the IRB submission date): mm/dd/yyyy to mm/dd/yyyy

1 July 2011 to 30 June 2012

9. Objectives of the study: (Primary endpoints of study, listed and numbered individually)

1. To determine the overall attributable cost of nosocomial infections in the intensive care unit
2. To determine the attributable costs of each nosocomial infection-Ventilator associated pneumonia, Blood stream infection, urinary tract infection and skin and soft tissue infections.
3. To determine the factors contributing to the difference in cost in patients with and without nosocomial infections

10. Confidentiality of data:

- a) Describe how data (both paper and electronic) will be stored to safe-guard confidentiality (e.g. in a locked cabinet, password protected computer):

Electronic data will be stored in the principal investigator's computer which is password protected.

b) Specify as to who will have access to harvested patient data: All the members involved in the study

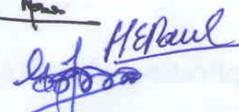
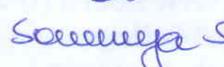
c) Clarify as to how harvested patient data will be stored and how it will be destroyed when no longer needed: Data will be stored electronically for 5 years and then subsequently deleted.

12. Name of statisticians involved in the analysis.-Nil

13. Informed Consent: (This is relevant for stored samples when used for the study)

14. Signature of Principal Investigator(s) / Co investigator(s) / Co-author(s):

I/We give my/our consent to be a Co-Investigator and provide my/our expertise to the project. I/We have approved this version of the protocol and have contributed substantially to its development. This study is purely retrospective without any prospective component. It does not involve analysis of novel therapy.

Name	Department	Signature	Date
Dr Binila Chacko	Medical ICU		9/3/2016
Dr Peter John Victor	Medical ICU		9/3/16
Dr Hema Paul	HICC		9/3/16 9/3/16
Dr Sowmya Sathyendra	Medicine 3		9/3/16
Dr Thambu David	Medicine 2		9/3
Dr Kurien Thomas	PIMS		Will submit shortly
14. Approval of Head of the Department:			9/3/16

(Not necessarily a coauthor / co investigator in this study)

Please list below all additional documents that are being submitted along with this application including all appendices.

Notes for filling in this form

1. The application is required for Research Committee Approval.
2. Please also read the **Standard Operating Procedure** of the IRB of CMC Vellore (available from the Research website) for additional guidance on policies and procedures that will be followed at CMC for IRB approval. Site link: [http://172.16.11.136/Research/IRB Polices.html](http://172.16.11.136/Research/IRB%20Polices.html) (or) [http://www.cmch-vellore.edu/static/research/IRB Polices.html](http://www.cmch-vellore.edu/static/research/IRB%20Polices.html).
3. Submission procedure
 - Project proposal
 - Curriculum Vitae(s)
 - **Signatures by all investigators and the Guide/Head of the Department/Unit need to be scanned.**

Applications submitted after the due date for the Silver IRB will not be entertained.

IMPORTANT:

Clearance for the study will be given only after the ratification in the Silver Institutional Review Board meeting.

The Investigators need not have to represent for the Silver Institutional Review Board for presentation.

Completed application with all supporting documents (Hard and Soft copy) should be submitted to

**Institutional Review Board (IRB)
Christian Medical College
Office of Research, I st Floor,
Carman Block, Bagayam, Vellore 632 002 India.**

E-mail: research@cmcvellore.ac.in.

Tel: 0416 -2284294, 2284202 Fax: 0416 - 2262788, 2284481.

**Hours for submission: 8.00 am to 5.00 pm (Monday - Friday)
8.00 am to 12.00 pm (Saturday)**