

Patient study Number:

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INFORMATION SHEET AND INFORMED CONSENT FORM FOR PARENTS/GUARDIANS OF PAEDIATRIC INPATIENTS (under 14yrs) TO PARTICIPATE IN A STUDY

INVITATION

You/ your child is invited to participate in a study aiming at determining the ***Impact of Bacterial Infections Resistant to Antibiotics*** to be carried out in [insert location]. In this study, we will collect medical data from you/your child to measure the link between antibiotic resistance status and patient outcomes (risk of patient death and length of hospital stay). This will be done for patients with proven bloodstream infections and also for some uninfected patients for comparison. This information sheet is for children under the age of 14years, both with and without bloodstream infection as the same forms of information will be collected for both groups.

PARTICIPATION IS VOLUNTARY AND DEPENDS ON YOUR WILLINGNESS

This document gives brief information to the participant and their patient or guardian. But if needed, more details about this study can be discussed between you/your child and a researcher. After this detailed discussion you will be asked to sign in a space provided below. Signing this document will mean that you have consented and you are willing to participate in this study. It is also important for you to understand that your participation in this study is dependent on your willingness, you will neither lose your rights to medical care nor will participation in this study cause you/your child to be denied any service provided within this health facility.

STUDY OBJECTIVES

This study will help:

1. To determine the risk of death for “appropriately treated bloodstream infection” versus their uninfected comparison patients and a similar measurement for “inappropriately treated bloodstream infection”.
2. To determine length of hospital stay for “appropriately treated bloodstream infection” versus their uninfected comparison patients and a similar measurement for “inappropriately treated bloodstream infection”.

WHAT IS NEEDED FOR THIS STUDY

This is a purely observational study mainly using routinely collected clinical information, participation will not require the collection of any additional samples or the administration of additional treatments. A research nurse or doctor will gather information from you/your child’s medical notes and you may be contacted by phone after leaving hospital about your child’s health. Some additional questions or measurements (eg. Height and Weight of you/your child) will be performed directly by research staff if these have not already been done by hospital doctors.

WHAT ELSE I SHOULD KNOW AS A PARENT/GUARDIAN OF A PARTICIPANT

If your child has an infection in the blood, the bacteria already identified from their blood will be stored at [insert laboratory name] for further studies. If you decide to withdraw your child’s participation from this study and you don’t want their specimen to be used, all their specimens will be destroyed as recommended. The use of your child’s specimens for the study entirely depends on your/your child’s willingness.

CONFIDENTIALITY OF INFORMATION

All information collected or generated during this study will be confidential. Access to study information will be restricted to research team only. Unique indication number, patient's initials and date of birth will be used to identify patients instead of names.

CONCLUSION

We recognize and thank you for taking your valued time to read, understand and consent to participate in this study. Please, you can freely ask any questions concerning this study for more clarifications any time should you want.

CONTACT DETAILS

Whenever you have any questions or if you want us to clarify more about this study, please contact one of the study team at [insert institution] or call [insert phone number]

Child's name (capital letters)

Parent/Guardian's name (capital letters)	Signature	Date
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Relationship of above to child		

Witness name (capital letters)	Signature	Date
		D D M M M 2 0 Y Y

Researcher's name (capital letters)	Signature	Date
		D D M M M 2 0 Y Y

Comments: