Appendix C: Consent Form

Burden of Antibiotic Resistance in Neonates from Developing Societies (BARNARDS)

Purpose of the study

You are being invited to participate in our study focussed on the burden of antibiotic resistance in neonates from developing societies. The level of antibiotic resistance in neonatal infections and its impact on mortality in low-middle income countries is unacceptably high. This study will provide the means, support, network and tools to understand the impact of antibiotic resistance on neonatal morbidity and mortality ***(in country)*** as well as to identify possible solutions to minimise its impact.

Procedure

Once we have obtained informed consent from you, a rectal swab will be collected from you and this this swab will be sent to the UK for screening. Your swab will be assessed for multi-drug resistance (MDR) (specifically ESBL and carbapenemase positive) Gram-negative bacteria. A rectal swab will be also taken from your baby if he / she develops early (≤72 hours) or late onset bacterial sepsis (>72 hours) and the results from your baby's swab will be compared to your results.

We will also require some basic demographic information and record antimicrobial therapy you were subjected to in the hospital. Our trained nurses will carry out the above mentioned procedure.

Possible risks or discomforts

There are no side effects of the study and the procedure will be discrete, quick and painless.

Possible benefits

No personal benefit, however it will improve the care and assessment of your child and provide long term strategies to improve health in ***(name country)***

Financial considerations

There is no financial compensation for your participation in this research but we'll do all laboratory tests of your sample free-of-charge.

Confidentiality

Your identity in this study will be treated as confidential. The results of the study may be published for scientific purposes but we will not give your name or include any identifiable references of you. Only the investigators of the study, data collectors will have access to your data. Your anonymity will be safeguarded under the rules we will adhere to in the Helsinki Declaration.

Termination of research study

It is important for you to understand that participation in this research is your own decision. You will decide whether you will take part in this study or not, and that you can withdraw from this study at any time during the research. This will not affect your present and future medical care in this hospital.

Available source of information

For any other problem or query please consult the local principal investigator of this study:

Name:

Email:

Telephone:

Address:

Authorisation

I have understood this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Name of the patient: ……

Signature: _____ Date: _____