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CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**: Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

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Study ID: HUM00120971 / Amendment ID: Ame00071558

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Sample Research Informed Consent Form

Title of Study: Optimizing Clinical Use of Polymyxin B: Teaching and Old Drug to Treat Superbugs

Principal Investigator (PI): *(insert site PI information)*

Funding Source: **NIH**

"You" in this form may refer to you or your legally authorized representative.

Study Purpose

This is a research study. This research study will not include any changes in the treatment of your disease, only blood and urine samples will be collected. You are eligible to participate because of the type of treatment you are already receiving. Your treatment will not change, regardless of whether or not you decide to participate in this study. If you choose to participate, your doctors currently caring for you will still manage your care.

You are being asked to participate in this study because you are receiving treatment for an infection (pneumonia, blood stream infection, urinary tract infection, tracheobronchitis or sepsis) with intravenous (IV) polymyxin B, a type of antibiotic.

The reason for this study is so researchers can look at the amount of antibiotic (Polymyxin B) that is in your blood to see if levels are high enough to treat your infection. Urine samples are being collected to see if any markers of kidney function problems can be detected while you are being treated with polymyxin B.

Please read this form and ask any questions you may have before agreeing to be in the study.

Study Procedures

If you meet all of the criteria for this research study the following will be done.

Information will be collected on you and your care from your medical record from the time you were admitted to the hospital until the final day that you are receiving polymyxin B and on the day that you are discharged from the hospital. We will be collecting information such as age, gender, race, prior antibiotics you received, temperatures, blood pressure and if you are on dialysis. Only deidentified data will be shared with the sponsor.

Blood samples will be collected for the purpose of research only. The samples will be collected between days 1 and 5 days after enrollment onto the study. The collection days will depend on how often you are receiving polymyxin B. A total of six blood samples (1/2 teaspoon each) will be collected during this time. In addition, patients who are on renal replacement therapy or intermittent hemodialysis will have 3 pairs of samples collected from their arterial and venous ports.

Urine samples will be collected for the purpose of research only. The samples will be collected after enrollment and 12-24 hours after enrollment. A total of 3 urine specimens will be collected.

Your original specimen (from your blood or sputum [fluid from your lung] or both) that was collected before you were approached for this study will also be sent to the researchers for further evaluation. This specimen is called a bacterial isolate and will be collected from the microbiology laboratory.

Other than data collection, blood and urine sample collection and the collection of your specimen from the microbiological laboratory no other treatment or care will be done as part of this study.

The blood and urine samples that will be collected from you are for research purposes and will be sent deidentified to Monash University in Australia to undergo laboratory testing.

Research Involving the Future Use of Biological Specimens

You have the right to withdraw your consent to store your specimen at any time by either requesting that your specimen be destroyed or that the coded identifier be removed.

Results from any future research will not be placed in your medical record.

Currently there is no benefit to you to allow the researchers to store your specimen(s) but there may be benefits to society in the future.

No human genetic testing will be performed on your specimens.

Make your choice below if you agree or disagree that your specimens can be stored for future use. You can choose to have your specimen(s) stored or not stored and still be in the study.

Agree _____/_____ Disagree _____/_____
Initials Date Initials Date

Benefits

Information from this study may benefit other people with these types of infections in the future.

Risks

The more common known risks of drawing blood includes discomfort or pain, bruising, bleeding at the site, nausea, lightheadedness, fainting. A less common known risk includes infection at the blood draw site.

Alternative

You have the alternative to choose not to participate in this study.

Study Costs

Participation in this study will be of no cost to you.

Compensation

You will not be paid for taking part in this study.

Research Related Injuries

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by *(insert per institutional policy)* and any other facility involved with this study. No long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government. If you think that you have suffered a research related injury, contact *(insert PI name)* right away at *(insert PI phone number)*.

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code number. Information that identifies you personally will not be released without your written permission. However, *(insert per institutional policy)*, or federal agencies with appropriate regulatory oversight [e.g., NIH, Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

Voluntary Participation and Withdrawal

Taking part in this study is voluntary. You may choose not to be in this study. If you decide not to be in this study, you will not be penalized and you will not lose any benefits to which you are entitled. You will still receive medical care.

Questions

If you have any questions about this study now or in the future, you may contact *(insert PI name)* or one of his/her research team members at the following phone number: *(insert phone number)*. If you have questions or concerns about your rights as a research participant, or if you want to talk with someone other than the research staff, you can call the Institutional Review Board (IRB) at *(insert phone number)*. You may also call the IRB to ask questions or voice concerns or complaints.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov.. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

Printed name of participant / Legally authorized representative	Date
Signature of participant / Legally authorized representative	Time
Printed name of person obtaining consent	Date
Signature of person obtaining consent	Time
Printed name of witness*	Date
Signature of witness*	Time
Printed name of translator *	Date
Signature of translator*	Time

*****Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

IRB number: IRB approved: