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OxTREC ref: 524-21

Participant Information Sheet (PIS)

ACORN: A Clinically-Oriented Antimicrobial Resistance Surveillance Network – Phase 2

"Infection surveillance to improve understanding of antibiotic resistance"

OxTREC reference number: 524-21

1. What's the purpose of this surveillance?

Antibiotic resistance is becoming a problem for treatment of infections in all parts of the world. The purpose of this surveillance is to collect basic information from patients with suspected infections and to link this information with the results of laboratory tests that have been done by the doctors treating them. This will help us better understand which patients are at most risk of antibiotic resistant infections and what the impacts of the resistance are. We will use the surveillance data to develop better antibiotic treatment and infection prevention guidelines. We are doing this surveillance in hospitals in Cambodia, Ghana, Kenya, Indonesia, Laos, Malawi, Nepal, Nigeria, and Vietnam.

2. Why have I been invited to take part?

We are doing surveillance in all patients admitted to [INSERT WARD NAMES HERE], if the doctor suspects an infection. Since this surveillance is collecting information that is part of normal medical treatment, we are asking you to tell us if you **do not want to take part or you do not want your child to be included.**

3. What's involved for me?

If eligible to be included in surveillance and you have not declined to participate, one of the surveillance team will collect some basic information from you about whether you / your child have any underlying medical problems, have been admitted to another hospital or had surgery recently.

The surveillance team will collect further information from your / your child's doctor and medical record about your / your child's infection and treatment.

When you / your child are discharged from hospital we will telephone you on one occasion to ask how you / your child are. This will happen approximately four weeks after you enter the surveillance.

4. What will happen to my data?

Data about you / your child will be collected using password protected smartphones / tablets. The data will be stored in an electronic database on a secure computer server, which may be located overseas. Only the surveillance team will be able to access the database. Institutional review boards or representatives from the surveillance sponsor, e.g. a monitor or auditor, may also have access to surveillance documents to make sure that the surveillance is properly conducted. This data will be deleted no later than one year after the end of the surveillance.

We will collect personal data (your / your child's hospital identification number, gender and data of birth) only to correctly match you / your child to the laboratory tests collected by your doctor. Once we have made this link and calculated your / your child's age, we will delete these personal identifiers and you / your child will be identified only by a surveillance code which cannot be linked back to you / your child. In order to contact you after hospital discharge, we will record your telephone number in a

paper logbook. This logbook will be kept in a secure location at [INSERT HOSPITAL NAME] and will be destroyed as soon as it is no longer needed.

Anonymised surveillance data will be kept indefinitely and will be shared with external organisations in the future: it will not be possible to identify you / your child from this data.

6. Are there any risks in taking part?

The only risk of taking part in this surveillance is loss of confidentiality, but we have processes in place to ensure that does not happen. As described above, personal data, i.e. things that could possibly identify you / your child, will be removed before data is moved outside of the hospital.

7. What are the benefits of taking part?

There are no direct benefits to you / your child on this admission if you take part in this surveillance. However, participating in surveillance will help [INSERT HOSPITAL NAME] improve patient diagnosis and treatment of antibiotic resistant infections. Use of surveillance data to better understand the risks, treatment, and prevention of antibiotic resistant infection is a major benefit to society.

There are no extra costs for you or your family if you decide to participate in this surveillance and you will not receive any expenses for participation in the surveillance.

8. Do I have to take part?

You may ask questions about the surveillance at any stage of you / your child's admission.

Whether or not you agree for you / your child take part is entirely your choice and this choice will not affect you / your child's clinical care at [INSERT HOSPITAL NAME].

If you do agree to take part, you may withdraw yourself / your child from surveillance without penalty at any time.

If you decide to withdraw yourself / your child from surveillance, the reason for withdrawal this will be entered into a logbook. However, you do not need to give a reason for withdrawal from surveillance. We will use any data collected up to the time of withdrawal, unless you decide that you don't want us to use data collected earlier.

9. Has the surveillance been reviewed by an ethics committee?

The surveillance has been approved by [INSERT DETAILS OF LOCAL EC / IRB] and the University of Oxford Tropical Research Ethics Committee in the UK.

10. What if I have any questions or want to raise a concern?

If you have any questions about the surveillance, please ask a member of the surveillance team or your doctor.

If you have any questions later, you can contact [INSERT DETAILS OF LOCAL PI].

If you feel that you / your child have not been treated as outlined in this document, or have any questions about your / your child's rights as a surveillance participant, you can contact [INSERT NAME] from the [INSERT LOCAL IRB NAME].

11. Data protection

The University of Oxford is responsible for ensuring the safe and proper use of any personal information you provide, solely for research purposes.