



**Austin Hospital Infectious Diseases Department Research Project**

**Participant Information and Consent Form for Adults in General Community:**

**Full Project Title:** Epidemiology of *van* gene carriage in health-care associated populations versus healthy controls.

Principal Researcher: Professor M. Lindsay Grayson

**1. Your Consent**

You are invited to participate in this research project because you are a healthy, non-hospitalised person. We would like to study how common it is for people who are not in hospital to carry a particular antibiotic-resistance gene called the “*van*” gene in their faeces, and to compare this with other populations, including Austin Health patients.

This Participant Information Form contains detailed information about the research project. Its purpose is to explain to you as clearly as possible all the procedures involved in this project before you decide whether or not you take part.

Please read this form carefully. Feel free to ask questions about any information in the document.

You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give consent to participate in the research project. Another adult will be required to sign as a witness to your signature.

You will be given a copy of this form to keep as a record. Participation in the study is entirely voluntary and can be terminated at any time without prejudice.

**2. Purpose and Background**

VRE (vancomycin resistant enterococcus) is an important antibiotic-resistant germ. The “*van* gene” is a gene in VRE that is responsible its antibiotic resistance. The purpose of this project is to improve our knowledge about how many people in the non-hospital general population carry bacteria in their faeces that contain the *van* gene, and to compare this with patients having dialysis and hospital staff.

Up to 1000 people will participate in this project. The study will include patients from The Austin Hospital and their families, as well as staff-members from the hospital. It will also include healthy adults and children not associated with hospitals.

While VRE generally only causes infections in patients with a poor immune system (such as those who have had chemotherapy or an organ transplant), healthy people can carry VRE in their bowel without it causing them any problems. We would like to study how many healthy people carry the *van* gene and how this differs from hospitalised people. We would also like to study which bacteria (including VRE) can carry the *van* gene. Recently we have shown that the *van* gene can also be carried in a number of naturally-occurring faecal bacteria other than VRE.

### **3. Procedures**

The study is being performed by the Infectious Diseases Department, Austin Health. Participation in this project will require each participant to give one faeces specimen for testing in the laboratory. The specimen will be tested for the presence of the *van* gene, and further tests will be done to identify which bacteria carry this gene. This will include testing for the presence of VRE and for other bacteria that normally live in the bowel called “anaerobes”. The study will also require each participant to fill out a simple (one-page) questionnaire with details such as age, sex, recent antibiotics taken, recent admissions to hospital and if there are any household members who work in a hospital. A copy of the questionnaire can be found below.

The faeces samples taken will be stored for at least seven years but with a label that would prevent you being identified in any way. The samples will only be used to help us study bacteria and antibiotic-resistance genes. They will not be used for any human genetics testing or other purpose, without additional approval being sought.

You do not need to change your diet or any other normal daily routine. You can still participate if they have medical problems or take medication – as many “healthy” people in the general population do this.

If you agree to participate, a special sterile container will be available for you to collect from four participating local pharmacies (listed below - see page 4). A researcher from the study will collect the containers from the pharmacy on Monday to Friday at 4pm. Please bring back the specimen container to these pharmacies only between 9am and 4pm on Monday to Fridays. The specimen should not be more than 24 hours old when you deliver it. A suggestion sheet on how best to collect the specimen is below (page 4).

### **4. Possible Benefits**

Although there is no direct benefit to you, the main benefits of this study are to help patients who have poor immune systems, since improved knowledge about the *van* antibiotic resistance gene may prevent these patients from developing serious infections with resistant germs.

### **5. Possible Risks**

As this study is an observational one, there is no greater risk than normal for people who are not in the study.

### **6. Privacy, Confidentiality and Disclosure of Information**

All information obtained in connection with this project will remain confidential and will be securely stored in a way that cannot identify you. These records would be destroyed after 7 years. If results of this study are published, again it will be done so that they cannot lead to you being identified.

### **7. Results of the Study**

The results of the study may be published in a medical journal in a way that cannot identify any of the participants. The results of the study *as a whole* can be made available on request to the Infectious Diseases Department. Your *personal* results however will not be available to you, since they are unlikely to have an impact on your health.

## **8. Further information or Any Problems**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact

Dr Maryza Graham (coordinator of this project) Phone: (03) 9496 5000 pager 6690, or

Prof. Lindsay Grayson (Principal Investigator) Phone: (03) 9496 6676

If you wish to contact someone, independent of the study, about ethical issues or your rights, you may contact Mr. Andrew Crowden, Chairperson of Austin Health Human Research Ethics Committee, Telephone 9496 2901.

## **9. Participation is voluntary**

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you participate, then later decide that you do not wish for your stored samples of stool to be used for any further testing, you are free to withdraw consent at any time (There is a Withdrawal of Permission Form for this purpose). Your decision to take part and then withdraw, will not affect your relationship with Austin Health.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

## **10. Ethical Guidelines**

This project will be carried out according to the *National Statement on Ethical Conduct in Research Involving Humans* (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of this Institution.

## **11. Reimbursement for your costs**

You will not be paid for your participation in this project.

Version: 2. Dated: 9<sup>th</sup> May 2005

## **Instruction sheet for faeces collection**

This is a suggestion sheet to help you collect your specimen in the easiest possible way.

The most important points are:

1. The faeces specimen is collected **WITHOUT** it touching the toilet bowl or toilet water
2. The faeces specimen should ideally not be mixed with urine. If mixing occurs (often unavoidable), please separate the faeces and urine as quickly as possible.
3. The specimen should be as fresh as possible (passed within 24 hours, preferably within 18 hours) before being delivered to the pharmacy.
4. The faeces specimen should be kept at **ROOM TEMPERATURE**. There is no need to refrigerate the specimen container after collecting the faecal specimen.
5. Place as much as possible of the specimen into the container but don't worry if the container is not completely full.

### **Suggested methods to collect faeces:**

**Method 1:** You can pass the faeces specimen directly into a clean ice-cream container and then transfer it into the brown-topped specimen container with the scoop provided (attached to the inside of the container lid).

**Method 2:** On the toilet with "Glad Wrap":

1. Raise the toilet seat and place a sheet of "Glad Wrap" (or similar) across the rim of the toilet bowl to stop anything from falling into the bowl. The "Glad Wrap" should not be tight – it should have a dip in the centre.
2. Place the toilet seat down. You can then sit as normal on the toilet seat.
3. Transfer the faeces specimen into the brown-topped specimen container with the scoop provided.

**Method 3:** On the toilet with "specimen collection sheet":

A specimen collection sheet is provided with the container in the bag along with instructions on how to use it. It is a biodegradable sheet that is placed in the toilet and can be flushed away.

**REMEMBER: Do not collect faecal specimens that have fallen into the toilet bowl or toilet water.** No matter how clean your toilet is, it will always contain some bacteria that will interfere with the study results.

Once the specimen is collected in the brown-topped container, place the container in the plastic specimen bag provided and seal the bag. Fill in your details on the **YELLOW** "Questionnaire" and place this in the side pocket of the specimen bag. Also place the completed **BLUE** "Consent form" in this side pocket. Then deliver the specimen bag to one of the participating pharmacies. Just walk in and ask the pharmacy staff where to leave the specimen.

Specimens can be left at the participating pharmacies between 9am and 4pm Monday to Friday until 16/09/2005 (please do not leave specimens outside of these times):

**Mounts Pharmacy:** 135 Upper Heidelberg Rd, Ivanhoe.

**Grace Pharmacy:** 110 Burgundy St, Heidelberg

**East Ivanhoe Pharmacy:** 254 Lower Heidelberg Rd, Ivanhoe East

**Rosanna Pharmacy:** 107 Lower Plenty Rd, Rosanna

If you have any questions please contact the study coordinator on the following number –  
Dr Maryza Graham Phone: 9496 6676 or 9496 5000 pager 6690.

Note: Please DO NOT fill in this form. This form is a copy for your information only. If you decide to participate in the study, please complete the identical BLUE form that is provided with the specimen container at the pharmacies listed below.

Version: 2  
Date: 09/05/2005



## Consent Form to Participate in Research

**Project Title:**  
**Epidemiology of *van* genes in health-care associated populations versus healthy controls.**

I, .....have been invited to participate in the above study which is being conducted under the direction of Professor Lindsay Grayson. I understand that while the study will be under his supervision, other relevant and appropriate persons may assist or act on his behalf.

My consent is based on the understanding that the study involves:

1. The participant giving one faeces specimen for testing in the laboratory.
2. The participant filling out a questionnaire (copy enclosed).
3. Tests being done to determine the carriage status of the antibiotic resistant bacteria VRE and its antibiotic resistance genes in this faeces specimen.
4. Storing samples of the participant's faeces.

The study may involve the following risks, inconvenience and discomforts to the participant, which have been explained to me:

No additional risks or procedures.

- I have received and read the attached 'Participant Information Sheet' and understand the general purposes, methods and demands of the study. All of my questions have been answered to my satisfaction. I understand that the project may not be of direct benefit to me.
- I can withdraw or be withdrawn by the Principal Investigator from this study/project at any time, without prejudicing my further management.
- I consent to the publishing of results from this study provided my identity is not revealed.
- I hereby voluntarily consent and offer to take part in this study.

Signature (Participant)	Date:	Time:
Witness to signature	Date:	Time:
Signature (Investigator)	Date:	Time:

**One copy to be given to participant,  
One copy filed in the research file.**

## **Participant Questionnaire – for adults in General Community**

*(To be filled out by the Participant)*

**PLEASE NOTE: This information will be kept confidential.**

**Please DO NOT write your name on this form.**

1. Your Date of birth: .....

2. Your sex: Male/Female

3. Date and time faecal specimen was passed:

Date:.....

Time:.....

Note: Please DO NOT fill in this form. This form is a copy for your information only. If you decide to participate in the study, please complete the identical YELLOW form that is provided with the specimen container at the pharmacies listed below.

4. Have you had any antibiotics in the last 2 weeks? YES/NO

If yes, what was the name of the antibiotic(s)?.....

How many days ago was this antibiotic stopped, or are you still taking it?.....

5. Have you been admitted to hospital in the last 3 months? YES/NO

If not, have you been admitted to hospital in the last 12 months? YES/NO

If yes, how long was each admission for?.....

On what date (approximately) were you last discharged from hospital?.....

6. Do you currently work in a hospital? YES/NO

If yes, please specify your occupation: Doctor/Nurse/Physiotherapist/Social worker

Other.....

7. Among your household members, is there anyone that works in a hospital? YES/NO

If yes, please specify their occupation: Doctor/Nurse/Physiotherapist/Social worker

Other.....

*After completing this form, please fold it and place it in the side pocket of the specimen bag, along with the signed BLUE Consent form. The faecal specimen container should be placed in the sealed section of this same bag.*