



1 September 2004

PARTICIPANT INFORMATION SHEET

This document is long however please take your time to read it.

Title of Project: An Investigation into the Effects of Psychological Stress on Primary and Secondary Antibody Response to Vaccination

Invited Participants: Medical students enrolled in year 2 and year 3 in 2005

Principal Researcher: Dr Mark Thomas, Department of Molecular Medicine and Pathology
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Researcher: Patricia Loft, PhD student, Department of Health Psychology
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You are invited to participate in a study of the effects of psychological stress on antibody response to Hepatitis B and Hepatitis A vaccination. You have been invited to participate in this study as testing for immunity to Hepatitis B virus infection, with subsequent offer of vaccination to those found to be susceptible to infection, is a routine part of the care offered you by the Student Health Service at the start of the second and third year.

The research that we invite you to participate in is a collaborative project between project members of the Departments of Health Psychology (Drs Keith Petrie and Rona Moss-Morris) and Molecular Medicine and Pathology (Drs Mark Thomas and Roger Booth). We wish to extend the results of a similar research project conducted with a previous third year class, which showed that an intervention (writing about emotional events) had a positive effect on antibody response to Hepatitis B vaccination. In this project we wish to determine whether the presence of a stressor (imminent exams), self-perceived stress (as measured by a brief questionnaire), or physiological response to a brief stressful event (heart rate, blood pressure, and salivary cortisol changes after a single inhalation of 35% CO₂) is the best predictor of the magnitude of antibody responses following Hepatitis B and Hepatitis A vaccination.

Participation in the research project is entirely voluntary. Participants may withdraw from the research project at any time before the study is completed on 1 September 2007. Neither grades nor any relationships with either the researchers or the researchers' departments will be affected by your participation or non-participation in the study or whether you subsequently withdraw from the study. Participation in the research will not involve any teaching time but will take place during lunch breaks or other free periods. Participation in the project will be confidential and students who choose not to participate will not be identified in any way.

All information gathered during participation in the research will be treated confidentially. If the information obtained from your participation in the project is reported or published, this will be done in a way that does not identify you as its source.

All information gathered in the course of the project will be stored in a locked cabinet and destroyed (by shredding of paper records and deletion of computer files) after a period of six years.

Outline of Study Procedures:

We hope that a total of 120 students will participate in the study.

1. Participant Recruitment

Year 2 and year 3 medical students will be asked to participate in this study. Recruitment of year 3 medical students will take place during the final semester of 2004 when students are still in year 2, and year 2 students will be recruited early in the first semester of 2005. Participants will be provided with information on the study, informed consent will be obtained, and participants will be randomly allocated to “exam” and “non-exam” groups on a 50:50 basis.

2. Baseline Procedures

The baseline procedures will be performed during weeks 2-3 of semester one 2005 for the “non-exam” group and 2-3 weeks before the first semester exams for the “exam” group. Baseline procedures include:

- (a) Participants complete a questionnaire measuring perceived stress, current health behaviours and a brief measure of social support (less than 10 minutes).
- (b) Measurement of physiological responses to a brief physiological stress task. You will be asked to take a single breath of 35% CO₂ and have your heart rate and blood pressure monitored for 5 minutes before and after the CO₂ inhalation. You will also be asked to provide a saliva sample immediately before and at 10 and 30 minutes after the CO₂ inhalation.
- (c) Participants provide a 5 ml blood sample at a Diagnostic Medlab collection site for measurement of serum antibodies to Hepatitis A and B

3. Vaccination

Vaccination will be given during the 1-2 weeks after the baseline procedures. The Student Health Service will give you low dose (quarter adult dose) Hepatitis A and Hepatitis B vaccinations.

4. Post Vaccination Measurement of Antibody Response

To be performed at 2 and at 6 weeks after vaccination.

We would like you to have a 5 ml serum sample collected at a Diagnostic Medlab collection site to measure your serum antibody response to vaccination. The results from these tests will be available to you through the staff of the Student Health Service. Any student exhibiting a poor antibody response to Hepatitis B or Hepatitis A vaccination will be contacted by the Student Health Services and offered a further vaccination.

5. Analysis

We will attempt to determine whether the presence of external stressors (i.e. imminent examinations), or perceived stress (as measured by the self administered questionnaire) or physiologic responses to stress (as measured by heart rate, blood pressure and salivary cortisol responses to inhalation of CO₂), best predicts the magnitude of serum antibody responses to antigens not previously encountered by the immune system (Hepatitis A vaccine) and to an antigen previously encountered by the immune system (Hepatitis B vaccine).

6. Presentation of Results

We will provide a summary of our results to all participants and intend to publish the results in an international peer-reviewed journal.

Beneficial Effects of Participation

1. Participants will learn whether they have immunity to Hepatitis A virus infection at the outset of the study (expected to be a very small minority of the subjects).
2. Participants will be given a Hepatitis A vaccine dose which will stimulate an initial antibody response and prime their immune system for a subsequent Hepatitis A vaccine should they subsequently require this vaccine (i.e. they will only require one dose of Hepatitis A vaccine in the future for lifelong immunity).
3. Participants will receive a single \$50.00 compensatory payment for the inconvenience caused by participation in the study. All participants will be provided with this payment regardless of whether they complete the project or not (i.e. there will not be any reduction in the compensatory payment if students withdraw from the study before completion).

Adverse Effects of Participation

1. Participation will require commitment of time to complete baseline procedures (approximately 45 minutes), to have the vaccinations (approximately 10 minutes) and to have serum samples collected (on three separate occasions, each approximately 10 minutes). The total time required by each participant to participate in the project is approximately 90 minutes.
2. Some participants may find the inhalation of a single breath of 35% CO₂ briefly unpleasant but not dangerous. If necessary, immediate first aid assistance will be provided by the researcher, who has attended a suitable emergency first aid training program. Any further assessment and treatment will be provided by Dr Mark Thomas or the staff of the Student Health Service.
3. Hepatitis A and Hepatitis B vaccinations are extremely safe and cause very little short-term discomfort at the site of injection.
4. Each of the three venepunctures to collect the serum samples can be expected to cause minimal local discomfort.

This project has been funded by the Auckland Medical Research Foundation with a grant awarded in December 2003.

The total time expected for participation in the project for each participant is approximately 90 minutes.

This project has been approved by the University of Auckland Human Participants Ethics Committee on 18 August 2004 for three years from 1 September 2004 to 1 September 2007, Reference Number 2004/294.