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Chair:
Associate Professor Alaina Ammit
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25 August 2009

Dr Devanshi Seth
Centenary Institute (Experimental Medicine)
Building 93
Royal Prince Alfred Hospital
C39
Email: devanshi.seth@email.cs.nsw.gov.au

Dear Dr Seth

Thank you for your correspondence dated 17 August 2009 addressing comments made to you by the Committee. After considering the additional information relating to this protocol, it was the Committee's opinion that there were no ethical objections to the project, and therefore recommends approval to proceed.

The approval of this project is conditional upon you adhering to the conditions outlined on Pages 2/3 of this approval, continuing compliance with the Animal Research Act (1985 – Animal Research Regulation 2005) and the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition 2004). Please sign and return the Acknowledgement of Approval (Page 4).

The project is approved for an initial period of 12 months with approval for up to three (3) years following receipt of the appropriate report (refer to Clauses 2.2.37 and 2.2.38 "Reporting of projects", of the Australian Code of Practice). Failure to submit reports will result in withdrawal of the project. **Your report will be due on 31 August 2010.**

Details of the approval are as follows:

Title:	Role of Opn in alcohol induced liver injury
Approval Number:	K75/8-2009/3/4978
Approval Period:	August 2009 to August 2010
Authorised Personnel:	Dr Devanshi Seth Associate Professor Mark Gorrell Dr Maria Wynne Mrs Margaret Gall Ms Marisa Mourelle

Species/Strain	Year 1	Year 2	Year 3	TOTAL
Mice – Opn gko in C57BL/6 background [males and females, 0-52 weeks old]				
Experiment 1 <i>“To characterize the effect of single dose of alcohol in wt and Opn-/- mice in the presence/absence of exogenous Opn”</i>				
Wild-type				192
Opn-/-				192
Experiment 2 <i>“To characterize the effect of multiple doses of alcohol in wt and Opn-/- mice in the presence/absence of exogenous Opn”</i>				
Wild-type				192
Opn-/-				192
TOTAL WT MICE [Repeated 3 x with n=4 animals per group per experiment (12 females and 12 males per group)]				384
TOTAL OPN-/- MICE [Repeated 3 x with n=4 animals per group per experiment (12 females and 12 males per group)]				384
TOTAL MICE				768

Animal House/Location

where Animals will be held: Centenary Institute Animal House

Conditions of Approval Applicable to All Projects

- (1) The Animal Ethics Committee (AEC) reviews and approves protocols for their compliance with the NSW Animal Research Act (and its associated Regulations) and the 2004 NHMRC Australian Code of Practice for the Care and Use of Animals for Scientific Purposes. All personnel named on the protocol should be conversant with these documents.
- (2) The approval is in accordance with your original submission together with any additional information provided as part of the approval process. Under **NO** circumstances may you or your Co-investigators depart from the approved protocol without the prior consent of the Committee.
- (3) Any changes to the protocol must be approved by the AEC before continuation of the experiment (Refer to website <http://www.usyd.edu.au/ethics/animal> under ‘Downloads’ for a Modification Form). This includes notifying the AEC of any changes to named personnel, source of animals, animal numbers, location of animals and changed to experimental procedures. The AEC approval number must be quoted when ordering animals from Laboratory Animal Services.
- (4) The procedures outlined in the protocol (including disposal of animals) must be strictly adhered to.

- (5) All cages/pens/tanks/paddocks used for holding animals must be clearly labelled with the Chief Investigator's Name, Approval Number, Title of Project, Short Description of the Project, Cage/Pen/Tank Number. Where electronic breeding records are kept instead of records on cage cards it is **essential** that printed copies of the records are placed in the relevant folder in the animals house, where they can be inspected by the AEC. These records **must** be updated regularly as breeding and husbandry events occur and current copies must be maintained in the animal house.
- (6) A copy of this approval letter must be supplied to the Animal House to be displayed where your animals are held.
- (7) If your protocol requires records of daily observations, these forms must be readily accessible in the Animal Holding Room (Animal House) at all times.
- (8) In the event of an unforeseen adverse incident (eg unexpected deaths), the Australian Code of Practice (refer to Clauses 2.2.28 and 3.1.12) requires that researchers promptly notify the AEC. Please refer to the website <http://www.usyd.edu.au/ethics/animal> under 'Downloads' for the form to complete "REPORT OF ADVERSE OR UNEXPECTED EVENTS DURING THE CONDUCT OF AN APPROVED PROJECT".
- (9) In the event an animal dies unexpectedly, or is euthanased due to unforeseen complications, an autopsy should be performed by a person with appropriate qualifications and/or experience and the AEC should be notified **promptly**.
- (10) Researchers should advise Animal House Staff if procedures are likely to result in overt clinical/behavioural abnormalities.
- (11) All animals must be provided with environment enrichment appropriate for their species.
- (12) Animals should not be housed singly unless approved by the AEC.
- (13) Animals must **not** be euthanased within sight or sound of other animals (refer to Clause 3.3.20, of the Australian Code of Practice).
- (14) The AEC will make regular routine inspections of the animals held by you.

Yours sincerely



Associate Professor Alaina Ammit
Chair
Animal Ethics Committee

Please complete and return to the Ethics Office, Level 6, Jane Foss Russell Building – G02, The University of Sydney

ACKNOWLEDGEMENT OF APPROVAL
Role of Opn in alcohol induced liver injury
K75/8-2009/3/4978

I DEVANSHI SETH agree/acknowledge the following:
PRINT NAME

Please tick:

☒ All Conditions of Approval that are set in the approval letter dated 25 August 2009.

☒ Personnel associated with the protocol. If training is required for any students (PhD, Masters, Honours) the Committee must be notified of their competency to do the tasks.

☒ The total number of animals that have been stated in the approval letter dated 25 August 2009.



SIGNATURE

DATE

25.8.09

ADDRESS FOR ALL CORRESPONDENCE
RESEARCH DEVELOPMENT OFFICE
LEVEL 3, BUILDING 92
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

TELEPHONE: (02) 9515 6766
FACSIMILE: (02) 9515 7176
EMAIL: lesley.townsend@email.cs.nsw.gov.au
REFERENCE: X09-0088 & HREC/09/RPAH/148

6 July 2009

Dr D Seth
Drug Health Services
Level 5, Building 14
Royal Prince Alfred Hospital

Dear Dr Seth,

Re: Protocol No X09-0088 & HREC/09/RPAH/148 - "Genetic factors that predict liver disease amongst excessive alcohol drinkers: a pilot genome wide analysis"

The Executive of the Ethics Review Committee, at its meeting of 25 June 2009, considered your correspondence of 2 June 2009. In accordance with the decision made by the Ethics Review Committee, at its meeting of 8 April 2009, ethical approval is now granted.

This approval includes the following:

- Information for Participants: Master Version 3, 28 May 2009
- Participant Consent Form: Master Version 2, 28 May 2009
- Data Collection Sheet (incl Form 01 (Alcoholic Cirrhosis), Form 01 (Heavy Drinkers without Liver Disease), Form 02 and Form 03): Version 2, 25 May 2009

You are asked to note the following:

- This approval is valid for four years, and the Committee requires that you furnish it with annual reports on the study's progress beginning in July 2010.

- This human research ethics committee (HREC) has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review and is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.
- You must immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project.
- You must notify the HREC of proposed changes to the research protocol or conduct of the research in the specified format.
- You must notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.
- Where appropriate, the Committee recommends that you consult with your Medical Defence Union to ensure that you are adequately covered for the purposes of conducting this study.

Should you have any queries about the Committee's consideration of your project, please contact me. The Committee's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Sydney South West Area Health Service website.

You are reminded that this letter constitutes ethical approval only. You must NOT commence this research project at ANY site until you have submitted a Site Specific Assessment Form to the Research Governance Officer and received separate authorisation from the Chief Executive or delegate of that site.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The Ethics Review Committee wishes you every success in your research.

Yours sincerely,



Lesley Townsend
Executive Officer
Ethics Review Committee (RPAH Zone)

ADDRESS FOR ALL CORRESPONDENCE
RESEARCH DEVELOPMENT OFFICE
LEVEL 3, BUILDING 92
ROYAL PRINCE ALFRED HOSPITAL
CAMPERDOWN NSW 2050

SYDNEY SOUTH WEST
AREA HEALTH SERVICE
NSW HEALTH

TELEPHONE: (02) 9515 6766
FACSIMILE: (02) 9515 7176
EMAIL: lesley.townsend@email.cs.nsw.gov.au
REFERENCE: X09-0088

5 August 2009

Dr D Seth
Drug Health Services
Level 5, Building 14
Royal Prince Alfred Hospital

Dear Dr Seth,

Re: Protocol No X09-0088 - "Genetic factors that predict liver disease amongst excessive alcohol drinkers: a pilot genome wide analysis"

HREC/09/RPAH/148

SSA/09/RPAH/352

Thank you for submitting a Site Specific Assessment Form for this study. I am pleased to inform you that authorisation has been granted for it to be undertaken at the Royal Prince Alfred Hospital.

The approved information and consent documents for use at this site are:

- Information for Participants (RPAH Version #1, 22 July 2009)
- Participant Consent Form (RPAH Version #1, 22 July 2009)

The following conditions apply to this research study. These are additional to those conditions imposed by the human research ethics committee (HREC) that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research, which may affect the ethical acceptability of the study and which are submitted to the lead HREC for review, must be copied to me.
2. Proposed amendments to the research protocol or conduct of the research, which may affect the ongoing site acceptability of the study, must be submitted to me.

I wish you every success in your research.

Yours sincerely,

A handwritten signature in cursive script that reads "Lesley Townsend". The signature is written in black ink and is positioned above the printed name and title.

Lesley Townsend
Research Governance Officer
SSWAHS (RPAH Zone)

RGO - Lesley\CORRES\X09-0088

ADDRESS FOR ALL CORRESPONDENCE
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EMAIL: lesley.townsend@email.cs.nsw.gov.au
REFERENCE: X03-0255
13.51/NOV10

12 November 2010

A/Professor P Haber
C/- Dr D Seth
Drug Health Services
Level 6, Building 13
Royal Prince Alfred Hospital

Dear Professor Haber,

Re: Protocol No X03-0255 - "The combined influence of alcohol and chronic hepatitis C on the human liver transcriptome"

The Ethics Review Committee, at its meeting of 10 November 2010, considered your annual progress report (10-11) on the above study, and it was noted with thanks.

Yours sincerely,



Lesley Townsend
Executive Officer
Ethics Review Committee (RPAH Zone)

HERC\COR10-11