



CENTRAL MANCHESTER LOCAL RESEARCH ETHICS COMMITTEE

Telephone: 0161 237 2152 Fax: 0161 237 2383 Email: Kate.Gardiner@mchester-ha.nwest.nhs.uk

Mr G Koumantakis
PhD Student
Centre for Rehabilitation Science
Manchester Royal Infirmary
Oxford Road
Manchester M13 9WL

05 May 1999

Dear Mr Koumantakis

The effect of general versus specific exercises on physical, functional and psychosocial parameters in sub-acute recurrent low back pain patients. A randomised controlled trial.

Ethics Committee Reference Number: CEN/99/040

Thank you for your letter of 19 April 1999 together with an amended patient information sheet, referral letter and list of protocol amendments. I have considered the amendments and/or documentation submitted in response to the Ethics Committee's earlier review of your application on 22 March 1999. Acting on behalf of the Committee I am now able to confirm final ethical approval for the study. The study should be started within three years of the date on which LREC approval is given.

The following items have been reviewed in connection with the study: ethical application form; protocol; revised information sheet; consent form; revised referral letter; sample GP letter; letters from CMHT R&D and Dr J Rankine.

Would you please note that granting of ethical clearance does not confer management approval for the study. This can only be given by your employing authority.

If the study is to take place in the Central Manchester NHS Trust and you have not already done so, you must contact the Trust's Research and Development Office in order to gain approval from the Trust. (Contact Mrs Tracy Watson, R&D Support Officer, Room 212 Cobbett House, Central Manchester Healthcare NHS Trust; Telephone: 0161 276 4125. Fax 0161 272 8837.)

MANCHESTER HEALTH AUTHORITY
Gateway House Piccadilly South Manchester M60 7LP

Tel: 0161-237 2000 Fax: 0161-237 2001

Professor Joan Higgins Chair
Neil Goodwin Chief Executive

Insurance cover is required for investigators who hold a substantive or honorary appointment with the University of Manchester and are involved in research studies on volunteers. If a project has been approved by an LREC, it only needs to be reported to the Senate Ethics Committee, in order that cover can be provided. (Please contact: Dr. TPC Stibbs, Secretary, Committee on the Ethics of Research on Human Beings. Telephone: 0161-275-6689).

You must notify any serious unexpected adverse events to the Ethics Committee. If any significant protocol amendments are proposed you must obtain prior approval from the Ethics Committee.

The Ethics Committee is required to monitor the progress of research studies and I will therefore be writing in about a year's time to ask you to complete a short review form.

Finally, please ensure that you quote the Ethics Committee reference number given at the top of this letter in any future correspondence.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'Dr E L Horsman', written in a cursive style.

Dr E L Horsman
Chairman

CENTRAL MANCHESTER HEALTHCARE TRUST

RESEARCH & DEVELOPMENT

PROFESSOR P DURRINGTON BSc MD FRCP FRCPath
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Director of R&D
Medical Education & Research Manager
Research and Education Support Officer
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Our Ref: TMW/lam/letters/671

16th April 1999

Professor Jackie Oldham
Centre for Rehab Science
MRI

Dear Jackie

Re: Research Project: The effect of general versus specific exercises on physical, functional and psychosocial parameters in sub-acute recurrent low back pain patients. A randomised controlled trial.

I am writing in reference to your query to whether the Trust would provide indemnity for the equipment involved in the above research project (which is not commercially available).

As it is a piece of equipment that has been designed and produced by yourself and Medical Engineering (and there has been no contribution from a commercial organisation), I can confirm that the Trust would provide indemnity for this research project through its insurance arrangements with the Clinical Negligence Scheme for Trusts.

If you require any further information please do not hesitate to contact me.

Yours sincerely

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Tracy M Watson
ACADEMIC SERVICES MANAGER

Turner Dental School

Dr T P C Stibbs
School Secretary
Tel: 0161 275 6689
Fax: 0161 275 6604



THE UNIVERSITY
of MANCHESTER

ref: TPCS/ethics/99016

21 June 1999

Mr G Koumantakis,
Centre for Rehabilitation Science,
M.R.I.

Dear Mr Koumantakis,

Committee on the Ethics of Research on Human Beings

99016 *Koumantakis, Oldham: The effect of general versus specific exercises on physical, functional and psychosocial parameters in sub-acute recurrent low back pain patients. A randomised controlled trial* (Manchester ref CEN/99/040)

I write to confirm that at its meeting on 18 May 1999 the Committee received the report on the above project which had been approved by a recognised ethics committee. That approval is therefore endorsed by the University Ethics Committee.

Yours sincerely,

Dr T P C Stibbs
Secretary to the Committee



Turner Dental School

University Dental Hospital of Manchester, Higher Cambridge Street, Manchester M15 6FH