

## SPONSORSHIP LETTER

GL/as

June 28, 2004

Peter D White  
Reader in Psychological Medicine

Dear Peter

Further to our recent correspondence on the issue of Sponsorship of the PACE trial, of which you are Principal Investigator, I would like to confirm that Queen Mary, University of London is prepared, under the Research Governance Framework for Health and Social Care, to take on the role of 'Sponsor' for the trial. QM will, for each participating site, delegate responsibility for Governance issues at local level, under a form of agreement to be completed by each site as they enter the trial. As principal sponsor, QM will ensure that governance procedures are centrally implemented and adherence monitored. The Joint R&D Office will be happy to assist you and your team with help in understanding their obligations under the RGF.

I hope this is helpful to you and would like to take this opportunity of wishing you every success with your study.

With kind regards and best wishes

Peter Davies

FINAL INDEMNITY

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Dear Professor P D White,

**Re: PACE: Pacing, graded Activity, and Cognitive behaviour therapy; a randomised Evaluation.**

Thank you for sending confirmation of your approval from the ethics committee. I am now happy to inform you that the College will indemnify against any negligence that might occur during the course of this project. Should any untoward events occur it is **essential** that you contact the R & D office immediately. If patients or staff are involved in an incident, you should also contact the Clinical Risk Manager on 0207 377 7653.

Please note that all NHS and social care research is now subject to the DoH Framework for Research Governance. If you are unfamiliar with the standards contained in this document, or the BLT policies that reinforce them, you can obtain details from the Joint R & D office (13-7250) or from the DoH Internet site. The address <http://www.doh.gov.uk/research/rd3/nhsrandd/researchgovernance/main.htm> will take you directly to the Research Governance Homepage.

As part of research governance, all investigators accessing individually identifiable personal information are required to comply with current information governance requirements. The Health Records Department in the Trust will not release patient notes for research purposes unless

- a) If you are a Trust member of staff (i.e. have a full or honorary contract) you produce this letter at the time you request batches of notes.
- b) If you are a researcher with no form of contract with the Trust you must produce a PIAG number, in line with Section 60 of the Health and Social Care Act. For further information on this section of the legislation you should contact the NHS Information Authority or your local Caldicott lead.

Please inform us if your project is amended and you need to re-submit it to the LREC / MREC or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records. For studies where the Trust is acting as sponsor you must send a copy of any monitoring/audit reports to the Research Governance and GCP Manager Gary Roper.

With best wishes.

Yours truly,



**Gerry Leonard, Head of Research Resources**

Queen Mary, University of London School of Medicine and Dentistry.  
The Royal Hospital of St. Bartholomew. The Royal London Hospital.  
The London Chest Hospital. The Queen Elizabeth Children's Service.