

Wednesday, 10 March 2010

Faculty of Medical and Human Sciences  
The University of Manchester  
Simon Building  
Brunswick Street  
Manchester  
M13 9PT

[www.manchester.ac.uk](http://www.manchester.ac.uk)

**To whom it may concern**

Sponsor Reference:

**Role of the Research Sponsor under the Research Governance Framework for Health & Social Care and the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031)**

I hereby confirm that the University of Manchester would be prepared to accept the role of research sponsor as currently defined in the *Research Governance Framework for Health & Social Care Version 2 (DoH 2005)* and the *Medicines for Human Use (Clinical Trials) Regulations 2004 (SI2004/1031)*, in relation to the study:

**"Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis MREC 00/8/053"**

I have been informed that this study will be led by **Professor Deborah Symmons & Dr Kimme Hyrich** of The University of Manchester.

Sponsorship is subject to the following conditions:

- 1) The lead investigator for the study must be an employee of the University of Manchester. For student research the academic supervisor is considered to be the lead investigator.
- 2) An appropriate contract must be agreed between the University and the funding body.
- 3) The research must be reviewed and approved by appropriate ethics, NHS and regulatory bodies and registered in accordance with University insurance requirements.

To enable the sponsor to meet their responsibilities as listed in section 3.8 of the Research Governance Framework, Chief Investigators are asked to adhere to the responsibilities as outlined in section 3.6 of the Framework [www.dh.gov.uk/research](http://www.dh.gov.uk/research). In line with this requirement **Professor Deborah Symmons & Dr Kimme Hyrich** must ensure that all involved in the research project understand and discharge their responsibilities in accordance with the agreed protocol and any relevant management, ethical and regulatory approvals.

Chief Investigators are also reminded that they must register NHS REC approval with The University of Manchester Research Ethics Office.

If you have any queries about sponsorship of this project then please address them to Dr Karen Shaw, Head of Research Office, The University of Manchester, Christie Building, Oxford Road, Manchester M13 9PL, or email [research-governance@manchester.ac.uk](mailto:research-governance@manchester.ac.uk)

Yours Faithfully,

**Mohammed Zubair**  
Faculty Research Practice Co-ordinator

Dated: 10-03-2010