

Sponsorship Approval Letter

Professor C Pitzalis
Department of Rheumatology
Barts and The London NHS Trust
Mile End Hospital
Bancroft Road
London
E1 4DG

Joint Research and Development Office
3rd Floor Rutland House
42-46 New Rd
Whitechapel
London
E1 2AX

Tel: 0207 882 7250
Fax: 0207 882 7276

15 November 2006

Dear Professor Pitzalis,

This letter is to confirm that **Queen Mary, University of London** will act as a sponsor for the project stated below.

Project title: Lymphoid neogenesis in rheumatoid arthritis: the histomorphological pattern of the synovial membrane (SM) predicts disease outcome

Chief Investigator: Professor Pitzalis

Sponsorship will remain in effect until the completion of the project and the ongoing responsibilities of the Chief Investigator as stated in the sponsorship agreement have been met.

Should the Chief Investigator fail to notify the Joint R&D Office of a substantial amendment to the project, this may result in incorrect indemnity or sponsorship cover and therefore the project may not be fully covered.

The sponsor may terminate this arrangement with immediate effect if:

- It is reasonably of the opinion that the project should cease in the interests of the safety of participants or staff involved in the project.
- The Chief Investigator is no longer (for whatever reason) able to act as Chief Investigator and no mutually acceptable replacement can be found.
- The Chief Investigator does not adhere to the responsibilities stated in the conditions of sponsorship letter.

Please see page 2 for more details of the conditions of sponsorship of the Chief Investigator.

For Multicentre Projects

It is the responsibility of all **Principal Investigators at each site** to ensure

- That they and all members of the research team comply with all current regulations applicable to the performance of the project including but not limited to, the NHS Research Governance Framework for Health and Social Care (April 2005), the World Medical Association Declaration of Helsinki (2000), the UK Medicines for Human Use (Clinical Trials) Regulations (2004), ICH Good Clinical Practice Guidelines (1997), the Human Tissue Act (2004) and the Data Protection Act (1998).
- Indemnity for negligent harm is obtained from their employing organisation.
- **Serious Adverse Events (SAE's) and Suspected Unexpected Serious Adverse Reactions (SUSAR's) must be reported within 24 hours of learning** of the event to the Chief Investigator at the Lead site and to your own local Research and Development Office.
- If the project is a clinical trial of a medicinal product, a sponsorship agreement with the Sponsor is signed.
- **Please use page 2 – the conditions of sponsorship of the Chief Investigator as a guideline for good research practice and ensure you adhere to your own Trust policies and R&D arrangements.**

Yours sincerely,



Mr Gerry Leonard, Head of Research Resources.

**Conditions of Sponsorship for the Chief Investigator
(Signed copy from Chief Investigator held on File)**

Queen Mary, University of London (QMUL) will act as a sponsor for the project stated below provided the Chief Investigator adheres to the following conditions:

- 1. The Investigator and all members of the research team shall comply with all current regulations applicable to the performance of the project, including, but not limited to, the NHS Research Governance Framework for Health and Social Care (April 2005), the World Medical Association Declaration of Helsinki (2000), the UK Medicines for Human Use (Clinical Trials) Regulations (2004), ICH Good Clinical Practice Guidelines (1997), the Human Tissue Act (2004) and the Data Protection Act (1998).**
- 2. The project must not start until:**
 - Favourable ethical opinion from an appropriately constituted LREC or MREC and MHRA approval (if applicable) have been obtained, or evidence has been provided that such approval is not necessary.
 - Final R&D approval has been obtained from the Joint R&D Office.
 - If the project is externally funded, financial arrangements must be covered by a suitable agreement approved and signed by the Joint R&D Office.
- 3. During the project, the Chief Investigator must ensure:**
 - Participants are consented to the project, using the version of the consent form and patient information sheet which has received a favourable opinion by the ethics committee.
 - Amendments to the protocol or project documents are approved by the ethics committee/ MHRA when applicable (see COREC website for guidance on substantial and minor amendments). The Joint R&D Office need to be notified of any changes and copies of the updated documentation and approval letters forwarded.
 - A project file is created containing all essential documents appropriate for the project.
 - The Joint R&D Office is notified of the actual start and end date of the project and any extension or early termination of the project. End of trial notification must be sent to the main REC and MHRA (if applicable) within 90 days of the conclusion date and within 15 days if the project is terminated early.
 - Appropriate Standard Operating Procedures (SOPs) are produced and followed for this project.
 - The Joint R&D Office is notified of any major staff changes to the research team and the delegation log is kept up to date.
 - Annual progress reports are sent to the sponsor and main REC.
 - All near misses and incidents stemming from the research if they occur on Trust premises are notified to the Trust Clinic Risk Department using the Trust incident form or if on QMUL premises to the Health and Safety Office using the Accident and Dangerous Occurrence Report Form. **Serious Averse Event (SAE's) and Suspected Unexpected Serious Adverse Reactions (SUSAR's) relating to clinical trials of drugs or devices must be reported to the Joint R&D Office and the main REC within 24 hours of learning of the event.** Safety reports must be sent to the sponsor, main REC and MHRA annually, if it is a clinical trial of an investigational medicinal product.
 - All project documentation, medical notes and staff involved in the research project are available for audit if requested by regulatory bodies or by the Joint R&D Office.
 - At the end of the project, documents relating to the project are archived within the Trust's archiving facilities. If the project is a phase I clinical trial of a medicinal product using healthy volunteers then please archive in the archiving facilities of your institute.
 - Any potential intellectual property stemming from the research must be disclosed to the Queen Mary Innovation & Enterprise Department.
 - The Joint R&D Office is notified of any outputs of the research such as guidelines, publications, changes in service delivery etc.
 - Any requests from the Joint R&D Office for further information on the project are responded to at the earliest convenience.