Barts and The London NHS
NHS Trust

Sponsorship Approval Letter

Dr Drew Provan
Room 417
Pathology and Pharmacy Building
80 Newark Street
London
E1 2ES

Joint Research and Development Office
24-26 Walden Street
Whitechapel
London E1 2AN

Tel: 0207 882 7250
Fax: 0207 882 7276

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Dear Dr Provan,

This letter is to confirm that **Barts and the London NHS Trust** will act as a sponsor for the project stated below.

Project title: United Kingdom adult Idiopathic Thrombocytopenic Purpura (ITP) registry: An investigation of disease progression, treatment effectiveness, and co-morbid conditions. UKITP

Chief Investigator: Dr Drew Provan

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. The incident should also be reported using the Trust specific incident reporting procedure.
- 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)

Barts and the London NHS Trust 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.
   - Non BLT employees having direct contact with patients and/or direct bearing of the quality of their care should ensure they have honorary contracts (see Trust policy).
   - If the project is externally funded, financial arrangements must be covered by a suitable agreement approved and signed by the Joint R&D Office. For any project which uses Trust resources, the Joint R&D Office must have assessed the associated costs and made arrangements for their recovery.

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 where applicable (see COREC website for guidance on substantial and minor amendments). The Joint R&D Office need to be notified of any changes to the project and copies of the updated documentation and approval letters forwarded to the Joint R&D Office.
   - 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 are notified to the Trust Clinic Risk Department using the Trust incident 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.
   - Any potential intellectual property stemming from the research must be disclosed to the London Innovations Hub (contact tel: 0207 380 1701).
   - The Joint R&D Office is notified of any outputs of the research such as guidelines, publications, changes in service delivery etc.
   - For research governance purposes, any requests from the Joint R&D Office for further information on the project are responded to at the earliest convenience.