**Dr. Sally Burtles**
**Joint Research Management Office**
Queen Mary Innovation Centre
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## Declaration of Sponsorship (Non-CTIMP)

18 November 2015

Professor Rupert Pearse
NIHR Research Professor & Consultant in Inte
Queen Mary University of London
Adult Critical Care Unit
Royal London Hospital
Whitechapel
London
E1 1BB

Dear Professor Pearse,

**Protocol:** **Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: A pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery.**
**Protocol version:** **1.4**
**Protocol date:** **18th August 2015**

**ReDA Ref:** **010443 QM**
**CSP:** **183040**
**REC Ref:** **15/LO/1595**

**Chief Investigator:** **Professor Rupert Pearse**

This letter is to confirm that **Queen Mary University of London** is willing to act as Sponsor as defined in the Research Governance Framework for Health and Social Care 2005.

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 Research Management Office of a substantial amendment to the project, this may result in inadequate indemnity or sponsorship cover and therefore the project may not be fully insured.

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 use page 2 (Conditions of Sponsorship) as a guideline for good research practice and ensure you adhere to any applicable Trust policies and R&D arrangements.**

Yours sincerely,

Dr. Sally Burtles
Director of Research Services & Business Development

Appendix 1 **Conditions of Sponsorship for the Chief Investigator (Signed copy from Chief Investigator held on File)**

**Appendix 1 Conditions of Sponsorship for the Chief Investigator**
**(Signed copy from Chief Investigator held on File)**

1. The Chief Investigator (CI) 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 (1996), the Human Tissue Act (2004) and the Data Protection Act (1998).

2. The project must not start until:

   2.1 "Favourable ethical opinion" from an appropriately constituted Research Ethics Committee (REC) has been granted.
   2.2 Non-Trust 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).
   2.3 All trial team members have attended an appropriate Research Governance course, commensurate with their role in the study.
   2.4 If the project is externally funded, financial arrangements must be covered by a suitable agreement approved and signed by the JRMO. For any project which **uses Trust resources**, the JRMO must have assessed the associated costs and made arrangements for their recovery.
   2.5 If the study is potentially eligible for the NIHR Clinical Research Network Portfolio, the application is processed through the NIHR Coordinated System for gaining NHS Permission.
   2.6 Appropriate contract(s) containing delegation of responsibilities are in place between third party sub-contractors and the Sponsor before that work begins.
   2.7 **"Final Sponsorship" has been obtained from the JRMO and, on an individual site basis, "R&D approval" has been obtained from research sites and copies provided to the JRMO.**

3. During the project, the Chief Investigator must ensure:

   3.1 The project is conducted in accordance with the protocol.
   3.2 Participants are consented in writing to the project, using the version of the consent form and patient information sheet which have received a favourable opinion by the Ethics Committee.
   3.3 The JRMO is notified of any major staff changes to the research team and the delegation log is kept up to date at all times.
   3.4 Amendments to the protocol or project documents are notified to the JRMO prior to submission to the REC. For further guidance see: http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/ .Research sites also need to be notified of any amendments, and approvals obtained where required, prior to implementation of the amendment.
   3.5 A Trial Master File (TMF) is created containing all essential documents appropriate for the project, making this available for monitoring, audit or inspection as required.
   3.6 The JRMO is notified of the actual start and end date of the project and any extension or early termination of the project.
   3.7 The JRMO is notified of the date of the first signed consent form (at any site if multi-centre).
   3.8 Written notice of any urgent safety measures taken to protect subjects of the trial is sent to the REC and Sponsor (within 3 days of learning of the event).
   3.9 Annual Progress Reports are sent to the REC and the Sponsor.
   3.10 Any other communication with the REC is forwarded to the JRMO.
   3.11 All near misses and incidents stemming from the research are notified to the Trust Clinical Risk Department using the Trust incident reporting form (http://bartshealthintranet/About-

Us/Corporate-Directorates/Nursing-and-Governance/Compliance-unit/Datix/Incident-reporting.aspx ).

3.12 Serious Adverse Events (SAEs) that are considered "related" and "unexpected" are reported to the Sponsor within 24 hours of learning of the event and the main REC within the required timeframe (http://www.hra.nhs.uk/resources/during-and-after-your-study/progress-and-safety-reporting/ ).

3.13 Serious breaches of GCP and the protocol are reported to the Sponsor within 24 hours of becoming aware of the breach.

3.14 All project documentation, medical notes and staff involved in the research project are available for monitoring/audit/inspection if requested by the Sponsor.

3.15 Appropriate Standard Operating Procedures (SOPs) are produced and followed for this project and the relevant Sponsor's SOPs are complied with.

3.16 Monitoring arrangements as outlined in the protocol and Sponsor's SOPs are complied with.

3.17 All relevant investigators and the REC have been notified of any findings which could adversely affect the safety of subjects, impact on the conduct of the study or alter the REC's favourable opinion.

3.18 Data is generated, recorded, handled, stored and reported accurately, securely and in accordance with the protocol, the Data Protection Act 1998.

4. When closing the project, the Chief Investigator must ensure:

4.1 An "end of study notification" is sent to the REC within 90 days of the conclusion date and within 15 days if the project is terminated early.

4.2 A summary of final report is submitted to the REC and Sponsor within one year of the study having been declared ended. http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/

4.3 Documents relating to the project are archived with the Trust's Modern Records archiving facility for a minimum of 20 years (http://bartshealthintranet/About-Us/Corporate-Directorates/Corporate-Affairs/Records-Management/Index.aspx

4.4 Any potential intellectual property stemming from the research must be disclosed as appropriate (http://www.nic.nhs.uk/Pages/NHSIPGuidance.aspx ),.

4.5 The JRMO is notified of any outputs of the research such as guidelines, publications, changes in service delivery etc.

4.6 For research governance purposes, any requests from the Sponsor for further information on the project are responded to at the earliest convenience.