University College London Hospitals NHS
NHS Foundation Trust

**Joint Research Office**

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**FINAL R&D APPROVAL – NHS PERMISSION**

07/06/2013

Mr Mohamed Sukeik
University College London Hospitals NHS Foundation Trust
235 Euston Road
London
NW1 2BU
UK

Dear Mr Sukeik,

Project ID: 11/0011 (Please quote in all correspondence)
REC Ref: 13/LO/0435
UKCRN ID:
Title: A randomised controlled trial of Polyglactin 910 Triclosan coated sutures versus standard Polyglactin 910 sutures in patients aged 18 or over undergoing primary unilateral hip and knee arthroplasties in the Department of Trauma and Orthopaedics at University College London Hospital

Thank you for registering the above study with the Joint Research Office (UCLH site). I am pleased to inform you that your study now has local R&D approval (NHS permission) to proceed and recruit participants at University College London Hospitals NHS Foundation Trust subject to sponsor confirmation.

Please note that all documents received have been reviewed and this approval is granted on the basis of the key documents provided which are ethically approved by the Research Ethics Committee:

| Document | Date |
|---|---|
| REC approval and REC approved documents | 03/06/13 |

As Principal Investigator you are required to ensure that your study is conducted in accordance with the requirements on the attached sheet. These include the conditions of your NHS permission.

Do not hesitate to contact a member of the team should you have any queries.

Yours sincerely

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**Professor Monty Mythen**
**Director of Research and Development**
**UCL/UCLH/Royal Free Joint Research Office**

# Responsibilities of the Researcher

**Conditions of NHS permission**

Your research has been granted NHS permission by the Joint Research Office on behalf of University College London Hospitals NHS Foundation Trust.

As a condition of the NHS permission you must comply with:

- Applicable Joint Research Office's Standard Operating Procedures
- Department of Health's Research Governance Framework for Health and Social Care
- Research Ethics Committee notice of favourable opinion
- Data Protection Act, Caldicott Principles and Trust Information Governance Policy.
- All other relevant legislation and regulatory approvals including the following *if applicable*
    - Medicines and Healthcare products Regulatory Agency
        - notice of acceptance of a clinical trial of investigational medicinal product (CTIMP)
        - notice of no objection of a clinical investigation for a medical device
    - Human Tissue Act 2004 and the Codes of Practice with special relevance to Code 9 Research
    - Human Tissue (Quality and Safety for Human Application) Regulations 2007

**Responsibilities for Research Teams**

As Principal Investigator you are required to ensure that:

- The roles and responsibilities of all members of the research team are documented in a delegation log and that all team members are made aware of these.

- All researchers conducting the study have applicable (up-to-date) honorary contracts.

- All researchers are suitably trained, qualified and experienced to carry out duties delegated to them and if conducting a clinical trial, have up-to-date Good Clinical Practice (GCP) training (updated every 2 years).

**Responsibilities for the Principal Investigator in relation to tissue and data in the absence of a study agreement:**

- After ethics approval for the study has expired, you shall ensure that tissues are disposed of in accordance with the protocol and Human Tissue Act 2004, transferred to a licensed tissue bank or used under a new ethically approved research project.

- Ensure that all necessary arrangements are in place for appropriate transfer, storage, handling, retention (archiving) and, if applicable, destruction of study data. The sponsor will act as the custodian of such data.

**Reporting on Recruitment**

Please ensure that you notify the Joint Research Office with:

- Confirmation of **recruiting your first patient** by emailing RandD@uclh.nhs.uk.

- There is also a requirement to report accrual on a regular basis. If your study has been adopted onto the NIHR portfolio you will be contacted directly by the NIHR Clinical Research Network Coordinating Centre. For all other studies you are required to provide an update to the Joint Research Office on recruitment every 6 months.

## Reporting Study Events

*Unexpected events and incidents*

Please ensure that your study team reports the following **to the sponsor** as required by the protocol or sponsor SOPs:

- For **CTIMPs**
  - All suspected unexpected serious adverse events (SUSARs),
  - Protocol violations, serious breaches of protocol and of GCP
  - Urgent safety measures
- For **all other studies**
  - All unexpected serious adverse events (SAE) related to the research protocol

Please ensure that your study team reports the following **to the Joint Research Office**:

- For **all research**
  - All complaints from NHS patients from UCLH should be reported in the first instance to the UCLH NHS Complaints Manager.
  - All research related incidents occurring at the UCLH should be reported through DATIX, the Trust Incident Reporting System (available on InSight).
- For **CTIMPs**
  - Please report all SUSARs and Serious Breaches of Protocol and GCP occurring at UCLH through DATIX.
- For **all other studies**
  - Please report unexpected SAEs related to the research protocol, serious breaches of protocol and GCP if applicable through DATIX.

*Study progress and changes*

Please ensure that your study team reports the following to the Joint Research Office:

- Amendments (including a request to extend the study)
- Monitoring activity information:
  - for non-commercially sponsored clinical trials provide a summary of corrective and preventive actions from monitoring reports, as agreed with the sponsor
  - for industry sponsored clinical trials provide a copy of the monitoring log on an annual basis, as agreed with the sponsor
  - annual progress reports submitted to REC (for UCLH sponsored research)
- Audit activity information:
  - Notification of audits or inspections
  - Audit reports (where possible, and in agreement with the sponsor, to provide a copy of the corrective and preventive actions arising from an audit)
- Notification of end of study or suspension of study
- Publications

### Study documentation

Research teams are required to:

- Prepare and maintain a site file to ensure that data and documentation associated with the study are available for audit. Please refer to the SOP for Preparation of Site File JRO/RM&G/SOP-13 available at: http://www.ucl.ac.uk/jro/standingoperatingprocedures

- Contact the Archivist & Records Manager by email as soon as the study has been suspended or ended in order to arrange for archiving.

If you require any further information on the above please see the Joint Research Office website http://www.ucl.ac.uk/jro.

**Joint Research Office Standard Operating Procedures are available at:**
http://www.ucl.ac.uk/jro/standingoperatingprocedures.