Please do not book your study with the Health Research Authority & MHRA prior to receiving written authorisation from the Research Governance Office.

A completed Sponsor Application form
Further information is required for CTIMPS*

A completed IRAS form (full dataset)

Study Protocol with version number & date including CRF¹

Participant documentation, information sheets, consent forms etc

Chief Investigator's CV (signed), GCP/Researcher Training Certificate

Peer review form & evidence of confirmation of adequate funding & research costs to be paid

Schedule of Events & Feasibility Assessment Form²

Further information available on applying for sponsorship
Please submit all to uolsponsor@le.ac.uk

Receipt of a valid application will be acknowledged & Sponsor Ref number allocated. A meeting will be required with the team for all CTIMP studies. All studies will be risk assessed which will include the

- Funding
- Consent
- Participant Information
- Data / Case Report Forms
- Randomisation
- Statistics
- Recruitment Strategies
- Protocol
- Questionnaires
- Safety Reporting
- Personnel
- Training
- Indemnity
- Equipment
- Laboratories
- Pharmacy
- Radiology
- External Vendors
- Contracts
- Monitoring
- Information Technology
- End of Study procedures
- Study Close down procedures

Depending on the Risk Assessment, the study may be referred to the Research Sponsorship Committee & Research Sponsorship Management & Operations Group. We will be in touch if further information is required and if changes are required to documentation.

Once HRA & MHRA* approvals have been received, Capacity & Capability Confirmation from each site & signed model non-commercial agreement; you will receive an agreed responsibilities Form, relevant signed contracts and Sponsor Green Light confirmation letter.

You will be required to copy the Sponsor into all correspondence in relation to your study with the HRA & R&D/R&I Offices.

Once Sponsor is in receipt of final documentation, you will receive an Indemnity Letter, Schedule of Events, Statement of Activities and authorisation to book your study with the Health Research Authority & MHRA*

*If Applicable

¹ If a CRF is being used, we will need to view it before Sponsor Green Light is given

² Can be completed in tandem with the Sponsor review process prior to submission to the HRA

Version 5 dated Sept 2017