



UNIVERSITY OF
BIRMINGHAM

Institute of Applied Health Research

Public Health Building

University of Birmingham

Edgbaston

Birmingham. B15 2TT

20th July 2024

To whom it may concern,

Re: CLARITY trial

Thank you for your organization's interest in participating in the CLARITY trial. A consultant surgeon at your hospital, has confirmed that they wish to be the Local principal Investigator for the **CLARITY** trial.

CLARITY is a multi-centre cluster randomised controlled trial which has been developed by the trainee-led West Midlands Research Collaborative and Professor Dion Morton from UHB (claritytrial.co.uk). The study aims to provide evidence on right Iliac fossa pain management in patients aged 16-40 years old admitted with suspected appendicitis, with the intervention being an educational package aimed at surgical teams, rather than at patients. The study will be led and delivered at sites by the surgical trainee networks and STARSurg, the medical student research network.

We would like to ask for your help in providing local R&D approval and have explained some key considerations below.

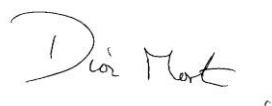
- The study is sponsored by the University of Birmingham and has already been granted HRA approval.
- The study will be managed by the surgical trials team at UoB, who are experienced in delivering surgical research studies, and who will coordinate sites and manage all data. All data collected will be held securely on REDCap within UoB. Only routinely collected, anonymised data will be uploaded on the REDCap system and no one, outside of the local clinical team will have access to patient identifiable information.
- The study will require no input from a research team at site. As the intervention is an educational package aimed at the surgical team, this will not incur any additional workload for either clinical or research staff or utilise any other hospital resources. The study is assessing training and aims only to provide the clinical

team with evidence on best practice for the treatment of patients with suspected appendicitis for their own decision making.

- Data will be collected by trainees, not research staff, and will be part of the trainee training programme, the educational package has been co-designed by the West Midlands Deanery.
- The study will last only 8 weeks at each participating centre.
- The study will adopted be on the NIHR portfolio.

There will be no additional requirements for support from your Trust for the collecting of data or identification of patients, this will instead be undertaken by, primarily, the trainees.

If you require any further information that might aid your decision making, I would be happy to contacted directly. My email address is dion.morton@uhb.nhs.uk. Thank you for considering this trial in your portfolio.
Yours sincerely,



Professor Dion Morton

Dion.morton@uhb.nhs.uk