**SURGICAL SPECIALTY LEAD**

Specialty-based trials development will be supported by Surgical Specialty Leads, who will have responsibility both for the development of clinical networks to deliver multi-centre studies as well as ensuring that the studies are relevant to their sub-specialty and their patients. Development and set up support will be provided by the Surgical Trials Centres.

These Surgical Specialty Leads will work with the Surgical Trials Centres to develop clinical networks, train the surgical investigators and deliver the clinical trials in a timely fashion. Each Surgical Speciality Lead will be affiliated to a specialist surgical society, with whom they will work to develop the clinical trials and clinical networks.

The key deliverables will be: to establish two new trials over their first three year tenure, to train up at least one new surgical chief investigator and twenty new principal investigators within their discipline. They would be expected to develop clinical networks that involved both consultants and registrars.

**JOB DESCRIPTION**

The Surgical Speciality Lead will act as a key link between the designated Surgical Trials Centres and national clinical research networks within their discipline. The Surgical Speciality Lead will be supported for three years to develop multicentre clinical trials within their area of expertise. In the first year, each Surgical Speciality Lead would be expected to work up two proposals with the trials centre and their clinical collaborative group, one of which would be taken forward to pilot phase and funding.

The Surgical Speciality Lead is expected to act as a conduit for interested clinicians and to provide a forum for discussion of proposals that can be processed through appropriate funding bodies. While the Surgical Speciality Lead is likely to lead at least one trial at the outset, it is expected that encouraging and developing other clinicians to lead future studies within that specialty will be a core objective. Support from the dedicated trials centre will be provided to work up proposals, prepare protocols, and develop CRFs and patient information sheets. Once a project is in the latter stages of preparation, the trials centre will also help prepare an IRAS application and oversee the acquisition of funding.

A Surgical Speciality Lead is expected to have experience in clinical trials and have a track record of involvement with a specialist network interested in clinical research. Clinical Research Initiative Steering Committee (CRISC), through the Director of Clinical Research, will work with the specialist associations to further develop surgical research networks, encompassing both consultants and trainees where appropriate.

A Surgical Speciality Lead will work closely with a designated trials centre and provide stewardship to their network of clinical researchers.

Surgical Speciality Leads will be expected to attend meetings at the Royal College of Surgeons of England twice a year to report developments and progress achieved. They would also be expected to chair a clinical research group to help develop new trials in their field. Such a group would usually be within a surgical society.

Each post will be evaluated on an annual basis with a report prepared for CRISC.

**SUPPORT**

The Royal College of Surgeons, with key partners, will provide a broad base of support for the Surgical Speciality Leads. Expert guidance in topic selection, developing multi-centre/multidisciplinary teams and trials management will be provided. It is envisaged that the Surgical Speciality Leads will work as a *clinical study group* using the NCRI model, to help develop ideas and disseminate best practice. Workshops for developing new surgical trials have been successfully developed through the MRC methodology hubs, and will be held to specifically support the Surgical Speciality Lead.

The Surgical Speciality Leads will be encouraged to work with their specialist organisation (association) and a specialist charity to help develop the clinical research networks.

The core funded Surgical Trials Centres will provide essential experience and expertise in trial development and set up.

The CLRNs will provide research infrastructure support for the individual centres participating in these portfolio trials.

The NIHR surgical specialty group will provide an infrastructure to ensure wide publicity for national participation in these portfolio studies.

**PERSON SPECIFICATION**

The successful candidate would be expected to be an accredited specialist within their field of clinical expertise with a track record of running multi-centre clinical studies, including randomised controlled trials. A track record of publication of multi centre studies would be beneficial.

Experience of developing multi-centre clinical trials, writing protocols, submitting applications to IRAS and applying for external funding would be expected.

The candidate would be expected to have experience of working with multi-disciplinary teams, developing and leading committees, along with evidence of project development and timely delivery.

Key qualities/experience

1. Academic track record in clinical or translational research
2. Experience of engaging with NIHR, research councils, and charities
3. Working knowledge of clinical trials and experience of working with trials centres
4. Creative and energetic team player
5. Effective interpersonal and time management skills
6. Evidence of delivering projects or activities to set time frames and budgets

**RESPONSIBILITIES**

Substantial support will be provided from the Institute and its partners to assist each Surgical Speciality Lead. The Surgical Speciality Lead will be directly responsible to the College Director of Clinical Research. An annual report on the programme will be submitted to the steering group by the Director. The activity of each surgical trials centre will be evaluated separately.

The steering committee will provide annual reports to funders, although it is envisaged that each Surgical Speciality Lead will work closely with specialist charities.

Each post will be renewable annually, based on satisfactory assessment of performance, with re-application every three years. It is envisaged that extension beyond six years would be exceptional.

**DELIVERABLES**

**Year 1**

* Develop working partnership with a new Surgical Trials Centre (or other recognised trials centre)
* Establish (multidisciplinary) working group and network of collaborating centres
* Engage, where appropriate, a trainee collaborative to help with study development and delivery
* Work up two potential multicentre studies, with one being taken forward for portfolio status and funding

**Year 2**

* Open first multi-centre study for recruitment
* Identify 15 participating centres and establish 15 surgical PIs
* Start recruitment

**Year 3**

* Open 2nd multi-centre trial and establish one new surgical CI
* Open (total) 20 participating centres and 20 surgical PIs
* Successfully recruit from 20 centres with target recruitment demonstrable for 500 patients by the end of year 4