

SUMMARY

The Urology Foundation (TUF), working in association with the British Association of Urological Surgeons (BAUS) and the Royal College of Surgeons of England (RCS), wish to develop clinical research infrastructure in Urology in the UK. We are seeking applications to establish centrally funded methodological support embedded within an existing Clinical Trials Unit (CTU). We are calling for proposals from CTUs experienced in delivering surgical or interventional trials or with a strong desire to develop such a facet to their unit. The CTU will be expected to provide essential multi-disciplinary support to develop study protocols and grant applications in the field of Urology.

The key deliverables for the award are outlined below.

The funding available may be used for costs of employment and expenses. It is anticipated that the CTU involved would have the opportunity to run and manage any trials developed through this initiative that result in successful funding awards from other funders. Priority will be given to CTUs that can demonstrate how the funding will increase their capacity for surgical trials beyond their current level.

BACKGROUND

With over 750,000 episodes of inpatient care a year in the UK, urology is a specialty faced with a high demand. Urology covers both surgical and medical management of all aspects of the health of the urinary tract in women and men, and the male reproductive system. Urologists manage six types of cancer and undertake 40% of the cancer diagnostics in the NHS. Kidney stones are uniquely painful and despite 20,000 patients a year needing an operation for removal of urinary tract stones, and 50% of patients developing recurrent stones, the field remains remarkably under researched.

There have been notable successes in urological research in the UK e.g. prostate cancer diagnostics, prostate cancer treatment trials, and ground-breaking translational research, but much of urological practice lacks level one evidence to guide practice. The current urology trials portfolio has shown a spirit of collaboration across the specialty which we look to harness with this initiative, by developing a portfolio of multicentre national clinical trials across the spectrum of urological disease.

The importance of multicentre clinical research in maintaining and developing a high quality service has been recognised by the NHS, which has ring-fenced £1 billion per annum (1% of the total health budget) for this purpose. Surgery in general and urology in particular currently attracts a disproportionately small proportion of this funding compared to the massive burden of urological diseases on NHS expenditure. Two key factors that have led to lack of trials in surgical disciplines are the complexity of surgical trials and the potentially hazardous and invasive nature of interventions.

We wish to address these challenges by enabling a urology trials infrastructure to support development of urological trials by securing sufficient methodological expertise and support. It is clear that huge patient benefits will be gained from a rapid expansion in urological surgery trials, by development of level one evidence providing the best guidance on treatment of urological diseases.

REQUIREMENTS FOR HOST CTU

The Host CTU will need to demonstrate:

- Senior-level commitment to support this initiative;
- Experience of developing and successful delivery of multi-centre clinical trials in surgery or other interventional specialties (or otherwise can demonstrate a significant interest in expanding their portfolio in urology and how this could be achieved);
- A track record in securing funding for clinical trials in collaboration with relevant parties.



The Host CTU will be expected to:

- Review direct applications for research projects from the urological community and provide multi-disciplinary methodological support through the project development and grant application stages;
- Run any trials successfully funded through this pipeline;
- Proactively provide support to PIs and CIs nationally and particularly support first-time PIs and CIs in order to build capacity and capabilities;
- Be UKCRC-registered, although applications from non-registered units with the necessary expertise will be considered;
- Collaborate with TUF, BAUS, other trials units and other relevant bodies to disseminate the outcomes of the host CTU's work and to raise awareness of the successes to TUF and to BAUS membership more broadly. This may involve presentations at BAUS Conference and associated meetings, and articles in the BJUI, other high impact journals and other relevant media;
- Identify an individual to be held accountable for the progress on the award; this shall include reporting developments and progress achieved through the grant, and senior representation at any meetings as requested (with due notice given by TUF). These reports may be circulated more widely within the urological community, and used for publicity purposes as required;
- Be part of a Host Institution that accepts and abides by TUF's standard terms and conditions of grant award. (These are available online alongside the present document).

SUPPORT

TUF will similarly designate individual(s) responsible for maintaining the relationship with the CTU. In consultation and collaboration with BAUS, TUF may conduct research prioritisation exercises and, where it has done so, will share the outcomes with the CTU.

EXPECTED OBJECTIVES in addition to milestones

Year 1

- Development of a working partnership between the base CTU, TUF and BAUS members.
- An open call to UK urologists to submit proposals for clinical trials.
- Marketing & publicity to urology departments/urologists that the CTU is open for applications.

Year 2

- Development of first major project(s)
 - Grant writing
 - Protocol development
 - Ethics submission

Year 3

- Open first multi-centre study for recruitment
- Start recruitment from multiple centres
- Develop 2nd and subsequent clinical trials
- Establish at least one new trainee co-applicant (Associate Principal Investigator)
- Open further participating centres (a minimum of 10-20) and at least 10-20 surgical PIs and Associate PIs

MILESTONES AND DELIVERABLES

Year 1

- Establish (multidisciplinary) working group for urology study development in two disease areas
- Develop associate PI schemes to enhance recruitment into trials
- Establish one new surgical CI

Year 2

- Submit two applications for potential multicentre studies in urology
- Establish one new surgical CI

Year 3

- Submit two applications for potential multicentre studies in urology



- Establish one new surgical CI

FUNDING AVAILABLE

The funding available is a maximum of £60,000 per annum. TUF will not support institution indirect costs (in line with Association of Medical Research Charities guidance).

Funding is available initially for three years. While we are, in principle, interested in funding the full grant of £180,000 over three years, we are in the first instance awarding the funding for the first year of £60,000, as per our usual grant-award practice. Confirmation of future years' funding is subject to satisfactory progress.

We will require thrice-yearly progress reports from the CTU (at 4, 9 and 12 months). Payment will be made in two tranches of 75% and 25%, on receipt of the Host Institution's appropriately itemised invoices. The future years' funding will be assessed based on the performance report received at the nine-month time point. Failure to provide a report by the deadline may delay a decision about continued funding of the project, and may jeopardise future funding. In addition, payments may be withheld if reports are not received. Payment of the invoice on the second tranche of the grant will be subject to receipt of a satisfactory year-end or final report.

The Urology Foundation is not specifying how the funds should be spent, but is looking for the applicants to outline the intended use of the funds in order to meet the aims and objectives of the programme.

HOW TO APPLY

There are two deadlines that interested CTUs must meet in order to apply.

1) An initial expression of interest will be due by **Friday 4 September 2020**. This should include the name of the CTU and institution, the names of the principal applicant, the names of any co-applicants and a single paragraph of support. Please send your expression of interest to Oliver Morris at omorris@tuf.org.uk

This information will be used to help us in our planning but does not form part of the assessment process. All those submitting an expression of interest should submit a full application as per the below.

2) Interested CTUs must submit their full application by **Friday 2 October 2020**, providing the following information:

- A letter (up to 2 pages) outlining:
 - the suitability and commitment of the CTU for working on the initiative
 - what TUF funding would be used for and how this would deliver the objectives outlined above
- Confirmation from an appropriate administrative authority at the host institution confirming the institution's acceptance of the terms and conditions of grant award if successful. (These are available online alongside this document.)
- A financial statement indicating the total grant request and proposed 3 year budgetary breakdown of grant (maximum of £60K per annum)

Applications will be reviewed and shortlisted by members of TUF SEC with representation from BAUS (but excluding any members with a conflict of interest - i.e. those members formally affiliated to applying institutions). **Interviews will be held in late October / early November 2020** for the shortlisted applications, which we will expect a senior representative of the CTU to attend. Further details of the interview process will be provided to shortlisted applicants. An appointment will be made by end November with a view to the unit being ready to start working by 1 January 2021.

To apply, please send all relevant documents to Oliver Morris at omorris@tuf.org.uk

