National Institute for Health Research

**Surgery Research Call: Specification Document**
**Applied Health Research in Surgery**

The National Institute for Health Research (NIHR) will issue a call for research on the evaluation of technology-driven implanted or implantable medical devices, surgical procedures or surgical services in February 2012.

This call is a key component of the NIHR response to recognition of the need for an increase in research-based evidence related to surgical productivity and to patient outcomes;

- Through supporting capacity building across a wide range of surgical disciplines and,
- Increasing the volume of high-quality research on the effectiveness, delivery and organisation of surgery and surgical services.

The following six NIHR managed research programmes will be participating:

- Efficacy and Mechanism Evaluation (EME)
- Health Services and Delivery Research (HS&DR)
- Health Technology Assessment (HTA)
- Invention for Innovation (i4i)
- Programme Grants for Applied Research (PGfAR)
- Research for Patient Benefit (RfPB)

Research proposals must be within the remit of one of the six participating programmes and applicants should carefully consider the remit described for each programme. Applications based on innovative study designs are particularly welcome.

- Applications to evaluate the comparative effectiveness of new procedures that would obviate the need for surgery will be considered.
- Clinical trials involving 'non-surgical' interventions, e.g. interventional radiology, gastroenterology, cardiology, etc., must include a surgical intervention as a comparator.
- The inclusion of patient views and experiences are considered important by each participating programme.
- Proposals solely to explore epidemiological or pathophysiological issues around conditions conventionally treated with surgery are not in the remit of this call.

In addition:

- Applications to the EME programme may include the exploration of mechanisms, as well as the steps needed to progress from early human studies to a stage suitable for use in an accredited clinical service. The initial stages of a project may include prospective clinical work or retrospective research utilising existing samples or data. However these findings should be used to inform a main evaluative clinical study, which should account for the majority of the funding requested. Where relevant the role of diagnostic tests

or devices may also be explored but should always be subsidiary to the main therapeutic intervention, one of the arms of which must involve surgery.

- The HS&DR programme welcomes research on quality and organisation of surgery, including aspects of workforce (such as substitution issues in the surgical team, including use of non-medical first assistants); patient safety, quality and patient experience (over and above ongoing work to develop and evaluate PROMS); delivery and organisation of services (such as organisation of daycase surgery and stand-alone surgical units, primary care support for post-operative care and delivery of acute pain services within hospitals) and studies around surgical productivity and processes (including service improvement initiatives, flow and design.
- The HTA programme is particularly interested in receiving applications for surgical trials that evaluate the clinical and cost effectiveness of technology-driven implanted or implantable medical devices or bio-engineered or artificial tissue replacements, but will consider any trial in the general area of surgery. Applicants may wish to establish whether some procedures currently in use are efficacious, effective or cost-effective compared to surgical or non-surgical alternatives.
- For applications to i4i the scientific evidence upon which the proposed project is based must have progressed beyond basic research. The proposed project must also be focused on a specific application, with the specific qualities or characteristics of the proposed technology defined. Proof of the scientific principle must have already been achieved. In exceptional cases and where technology from a sector other than health is being investigated, proposed projects may look to obtain technical feasibility. Project teams should have the demonstrable experience to carry out all aspects of developing the proposed technology, scientifically, clinically and commercially. Where there are known gaps, applicants should explain how they plan to address these.
- Applications to PGfAR are likely to describe substantial programmes of research involving a number of discrete but inter-related components or activities which together have potential for benefits to patients and the NHS within 3 – 5 years of the end of the grant.
- Applications to RfPB should arise from daily practice in the NHS and must demonstrate a trajectory to patient benefit in the short to medium term. The programme supports applications which are regionally derived and applications for feasibility and pilot studies are welcome.

For further information on the participating programmes please visit:
www.nihr.ac.uk/research/Pages/Surgery.aspx

Application forms will be available from **Thursday 23 February 2012**. Completed forms must be submitted by **Friday 25 May 2012**. Funding decisions will be made no later than the end of March 2013.