HRB-TMRN Study within a Trial (SWAT) FUNDING 2019

Guidance Notes

Opening Date: 2nd December 2018

Closing Date: 8th March 2019 at 1pm

Background

Since September 2014, the HRB-TMRN has been working to strengthen the methodology and reporting of trials in health and social care on the island of Ireland so that they become more relevant, accessible and influential for patients and other service users, practitioners, policy makers and the public. This is being achieved through a programme of work relating to the methodology of trials and focused on (i) support (ii) training and education and (iii) research and innovation.

Where randomisation is possible, randomised trials are regarded as the most effective means of evaluating the effects of health care interventions. They have the potential to provide reliable and robust estimates of the effects of healthcare interventions to help people make well-informed decisions about care options. However, there is relatively little work being done on improving how randomised trials are designed, conducted, analysed, reported and disseminated. The study within a trial (SWAT) initiative is one approach to providing evidence to improve the efficiency of trials. The SWAT programme involves smaller studies focused on trying to find better ways to do trials into host trials.

Please see the following guidance document for a brief definition of SWATs, an explanation of why they are important and some practical 'top tips' that come from existing experience of doing SWATs <u>https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2535-5</u>

Scope of the current call

The scope of the current call is to facilitate the embedding of a study within an ongoing trial. The SWAT should address an independent methodology research question on either the design, conduct, analysis, reporting or dissemination of trials, for which there is current uncertainty and a need to provide evidence to support alternative ways of delivering or organising trial processes. The primary purpose of process evaluations it to assess fidelity, implementation, causal mechanisms and contextual factors rather than address a primary trial methodology question and process evaluations are therefore not eligible for this particular call.

Number of awards

One award is available of up to €25,000, inclusive of 25% overheads. Overheads are calculated as 25% of direct project costs. Award duration is for up to 12 months and strict timelines will apply.

Who should apply

Trial investigator teams working on a planned or an ongoing randomised trial are invited to apply. Approval for the SWAT application must be obtained in writing from the Principal Investigator for the host trial.

The award must be held and managed within one of the following HRB-TMRN institutions (each of whom have contributed to HRB-TMRN funding);

- National University of Ireland Galway
- University College Cork
- Trinity College Dublin
- University College Dublin

Lead applicants not based within these institutions may apply provided there is financial management support agreed with one of the HRB-TMRN institutions listed above through a nominated collaborator. Please contact the HRB-TMRN Programme Manager for further information.

Eligibility criteria

- Applicants must be registered members of the HRB-TMRN Clinical Trial Expertise Database (C-TED);
- Applicants must provide evidence from host institution of provision for funding for the planned / ongoing host trial (letter from research office).
 - In the event that the host trial is not reliant on funding, please contact the HRB-TMRN Programme Manager;
- Applicants must provide evidence of mentoring arrangements (where appropriate) to provide academic and clinical/practice-based support;
- Research funding awarded must be managed in a separate reportable account;
- Applications must include a named collaborator from the Medical Research Council (MRC) Trials Methodology Research Partnership. A request for a collaborator can be

made by forwarding an abstract (300 words) of proposed SWAT to the HRB-Trials Methodology Research Network at <u>hrb-tmrn@nuigalway.ie</u> prior to 22nd Feb 2019.

Budget

Allowable costs include;

Salary (salary, PRSI, pension contribution)

Applicants should use the IUA website for the most up-to-date recommended salary scales for academic researchers (<u>http://www.iua.ie/research-innovation/researcher-salary-scales/</u>). Please note <u>employee</u> pension contribution of 5% has already been incorporated into the IUA gross salary figure. Please state the pay scale used and the level and point on the scale. This should be justified accordingly.

The HRB-TMRN does not provide funding for the salary or benefits of academic staff within research institutions who are already in receipt of salary or benefits. The HRB-TMRN does not provide salary or buy out time for collaborators.

Employer's contributions to PRSI and/or national insurance at the appropriate rates (e.g. PRSI is calculated at 10.85% of gross salary in RoI).

Pension provision up to a maximum of 20% of gross salary will be paid to the host institution to enable compliance with the Employment Control Framework (an additional 5% employee contribution are part of the salary). The level of employer contribution should be in accordance with the model adopted by the host institution.

Running costs

For all costs required to carry out the activities. Access to necessary special facilities or services which are not available in the host academic institutions. Funding for small items of equipment can be included in this section. Standalone computers will **not** be funded. All costs must be inclusive of VAT, where applicable.

Dissemination and knowledge exchange costs

This covers costs associated with the Dissemination and Knowledge Exchange Plan – i.e. Seminar/conference attendance (provide details of name and location, where possible) and any other means of communicating outcomes or engaging with stakeholders.

Overhead contribution

In accordance with the HRB Policy on Overhead Usage, the HRB-TMRN will contribute to the indirect costs of the research through an overhead payment of 25% of Total Direct Modified Costs for both lab/clinical and desk based research. The following items are included in the overhead contribution: recruitment costs, office space, software, bioinformatics access.

Deadline

The deadline for submission of complete applications is: 8th March 2019 at 1pm.

Queries relating to this application can be sent at <u>hrb-tmrn@nuigalway.ie</u>

All application forms must be submitted as a PDF by email, along with relevant documentation to hrb-tmrn@nuigalway.ie by the deadline with '**SWAT AWARD'** in the subject line.

Peer Review Process

Applications will be subject to external peer review. Successful applicants will be notified by Monday 15th April 2019.