Study within a Trial (SWAT) FUNDING 2025

Special Call

In collaboration with:

Guidance Notes

Opening Date:	**08th November 2024**
Closing Date:	**03rd February 2025 at 1pm**
Notification of outcome:	**24th February 2025**

Background

The HRB-TMRN works to strengthen the methodology and reporting of trials in health and social care in Ireland so that they become more relevant, accessible and influential for patients and other service users, practitioners, policymakers 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 (iii) Research and Innovation, and (iv) Public Engagement.

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 a need to improve how randomised trials are designed, conducted, analysed, reported and disseminated. The study within a trial (SWAT) initiative is one approach to providing evidence to meet this need.

SWATs are embedded studies that evaluate different approaches to conducting clinical trials. These methodological studies are typically nested within larger 'host' trials. While SWATs offer valuable insights into trial optimisation, their implementation remains limited. More replications across diverse trial settings are needed to build a robust evidence base to effectively guide future trial design and conduct.

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

The MRC Northern Ireland Hub for Trials Methodology SWAT Repository is an online database of ongoing SWATs and provides further information and ideas for SWATs.
https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/

A coordinated approach to undertaking SWATs of monetary incentives

The HRB-TMRN are collaborating with the Implement SWATs team at the University of York, UK, who are coordinating a series of randomised SWATs evaluating the effectiveness and cost-effectiveness of different variations of monetary incentives for recruiting or retaining trial participants. Implement SWATs is a programme funded by the UK National Institute for Health and Care Research (NIHR), which aims to develop and promote the use of evidence for recruiting and retaining participants in randomised trials using SWAT methodology. This is to help more people participate in trials, speed up evidence for health treatments and reduce research waste.

Scope of the current call

This funding call aims to support the integration of a SWAT into an existing trial to evaluate both the effectiveness and cost-effectiveness of using monetary incentives for recruiting or retaining trial participants.

Monetary incentives, such as offering participants cash or vouchers, could potentially boost participant recruitment and retention in trials. Research priority-setting exercises have identified monetary incentives as promising strategies to test for their effectiveness in recruiting and retaining trial participants [1,2,3]. Previous studies (UK) suggest that offering incentives between £5 and £100 might improve participation, but the evidence remains limited [4,5]. Questions remain about the ideal amount and type of incentive including cash, vouchers, charitable donations, or payment cards that can be used in place of cash (e.g., ClinCard)—as well as their cost-effectiveness.

Eligible SWAT strategies

Applications should address one or more research questions regarding monetary incentives for participant recruitment or retention, as detailed in Table 1 (recruitment) and Table 2 (retention).

All applications must evaluate both the effectiveness and cost-effectiveness of the proposed incentive strategies. Applicants are encouraged, where possible, to include a process evaluation to explore the ethics and the processes around using and implementing the monetary incentives in their trial, though this is not mandatory. (See ***Additional Research*** on page 10).

Note on incentive amount:
The recommended minimum incentive is €10. Host trials may adjust this amount based on consultation with their trial team and Patient and Public Involvement (PPI) partners, provided the total SWAT budget remains within the €10,000 limit.

Table 1: Potential recruitment research questions

Question number	Recruitment research questions
1	What is the effectiveness and cost-effectiveness of a *€10 unconditional cash or voucher* incentive versus no incentive (i.e., the usual invitation) for increasing participant recruitment rates?
2	What is the effectiveness and cost-effectiveness of a *€10 conditional cash or voucher* incentive versus no incentive (i.e., the usual invitation) for increasing participant recruitment rates?
3	What is the effectiveness and cost-effectiveness of a *€10 unconditional cash or voucher* incentive versus *€10 conditional cash or voucher* incentive for increasing participant recruitment rates?
4	What is the effectiveness and cost-effectiveness of a *€10 cash or voucher* incentive versus *€30 cash or voucher* incentive for increasing participant recruitment rates?
5	What is the effectiveness and cost-effectiveness of a *€10 charitable* donation on behalf of potential participants versus no charitable donation (i.e., the usual invitation) for increasing participant recruitment rates?
6	What is the effectiveness and cost-effectiveness of a *€10 cash or voucher incentive* payment to potential participants versus *€10 charitable donation* on behalf of potential participants for increasing participant recruitment rates?

Table 2: Potential retention research questions

Question number	Retention research questions
7	What is the effectiveness and cost-effectiveness of a *€10 unconditional cash or voucher* incentive versus *€10 conditional cash or voucher* incentive for increasing participant retention rates?

8	What is the effectiveness and cost-effectiveness of a *€10 cash incentive vs €10 voucher incentive* for increasing participant retention rates?
9	What is the effectiveness and cost-effectiveness of a *€10 cash or voucher* incentive versus *€30 cash or voucher* incentive for increasing participant retention rates?
10	What is the effectiveness and cost-effectiveness of a €10 cash or voucher incentive at *two timepoints* versus €10 cash or voucher incentive at *one timepoint* for increasing participant retention rates?
11	What is the effectiveness and cost-effectiveness of a *€10 charitable* donation on behalf of potential participants versus no charitable donation for increasing participant retention rates?
12	What is the effectiveness and cost-effectiveness of a *€10 cash or voucher incentive* payment to potential participants versus *€10 charitable donation* on behalf of potential participants for increasing participant retention rates?

Publication strategy and data sharing

Applicants must commit to publishing their SWAT findings.
The Implement SWATs team can assist the host trial team in:

- Data analysis.
- Providing documentation on the development of the interventions.
- Background literature and context.
- Meeting SWAT reporting standards.

In recognition of these contributions, relevant members of the Implement SWATs team must be included as co-authors on resulting publications subject to all authors meeting International Committee of Medical Journal Editors criteria.

In addition to individual SWAT publications, teams must participate in collaborative analyses combining multiple similar SWATs. These will take two forms:

1. Simultaneous SWAT publications
2. Meta-analyses of related SWATs

The Implement SWATs team will lead these collaborative publications, with host trial team members included as co-authors. Examples of such collaborative analyses are listed in the reference list[6,7,8,9].

Data sharing requirements:
Teams must provide anonymised individual patient-level data (IPD) to the Implement SWATs team to enable IPD meta-analysis. This requires:

- A collaboration and data-sharing agreement
- Complete anonymisation of all patient data

Where IPD sharing is not feasible, comprehensive summary data must be provided.

Number of awards

One award of up to €12,500 in 2024 is available, inclusive of institutional overhead costs of 25% of direct project costs. The award duration is up to 12 months, and strict timelines will apply.

Who should apply?

Applications are welcome from research teams conducting planned or ongoing randomised trials.

Lead applicant requirements

- Can be at any career stage including early-career researchers with evidence of appropriate mentoring.
- Must be employed at a recognised HRB host institution.
- Must provide evidence from the host institution of provision for funding for the planned / ongoing host trial (letter from research office).
    - If the host trial is not reliant on funding, please contact the HRB-TMRN Programme Manager (hrb-tmrn@universityofgalway.ie).
- Must not have received previous HRB-TMRN SWAT funding. Applicants successful in any other HRB-TMRN funding stream are eligible to apply.
- Must provide evidence of mentoring arrangements (where appropriate).
- Must include a named collaborator from the Implement SWATs team at the University of York. Lead applicants can request a collaborator by contacting swats-group@york.ac.uk before submitting the application. The Implement SWATs team will also provide advice on the compatibility between the host trial and the proposed SWAT question.

Host trial requirements

- Must complete SWAT before March 2026.
- For retention SWATs, participants in the host trial must have at least one follow-up remaining.
- The team must commit to:
    - Obtaining necessary ethics approval (see below).
    - Following the shared randomisation protocol.
    - Share anonymised data with the Implement SWATs team.
    - Publish the SWAT findings.

Financial management

- The award must be managed in a separate reportable institutional account.
- For host trials without external funding, contact the HRB-TMRN Programme Manager at hrb-tmrn@universityofgalway.ie.
- The relevant Institution must provide evidence of having systems and processes in place to distribute different types of participant incentives in accordance with the randomisation protocol, including:
    - Cash payments.
    - Digital or physical vouchers.
    - Charitable donations on behalf of participants.
    - Conditional and unconditional payments.
    - Process payments in a timely manner that aligns with the SWAT protocol timing requirements (e.g., ability to process unconditional incentives before recruitment or conditional incentives after specific milestones).
    -

The award must be held and managed within one of the following HRB-TMRN affiliated institutions;

- **University of Galway**
- **University College Cork**
- **Trinity College Dublin**

- **University College Dublin**
- **University of Limerick**

Applicants from other Irish institutions may apply if they:

- Establish financial management support through one of the above institutions.
- Identify a nominated collaborator at the managing institution.

Please contact the HRB-TMRN Programme Manager (hrb-tmrn@universityofgalway.ie) for further information.

Benefits

- Advance trials methodology by contributing to the evidence base on recruitment and retention in trials. Evidence from these SWATs will be included in the Cochrane systematic reviews of recruitment and retention strategies and will inform the development of guidelines for effective recruitment and retention in trials [4,5].
- Opportunity to collaborate with the Implement SWATs team based at the University of York, who will provide support to undertake the SWAT, including support and advice for the ethical approval processes and template/example documents to ensure ease of implementing the SWAT.
- Raise the profile of your trial through greater research outputs and collaboration.
- An opportunity to get involved in an international initiative.
- An opportunity for trial team members to lead an embedded study with the host trial.
- Maximising the research questions the trial can answer will ultimately improve future trials' recruitment or retention processes.
- Access to current thinking on effective recruitment and retention strategies.
- Acknowledgement in Implement SWATs collaboration reports, dissemination and publications.
- Authorship of SWAT publications.

Ethical approval

Successful applicants must obtain ethical approval after receiving notification of funding and before starting the SWAT. This process should adhere to standard ethical research practices and comply with the host institution's ethics committee requirements.

SWAT registration

We require all funded SWATs to be registered on the MRC-HTMR All-Ireland Hub website.

Budget

Budget is for eligible spending in Republic of Ireland only. Subcontracting of activities to organisations outside of Ireland is not permitted.
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 (http://www.iua.ie/research-innovation/researcher-salary-scales/). Please note an employee 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 buyout time for collaborators.

Employer's contributions to PRSI and/or national insurance at the appropriate rates (e.g. PRSI is calculated at 11.05% of gross salary in the Republic of Ireland).

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, including staff time, data anonymisation and incentives.
- 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 desk-based research. The overhead contribution includes the following items: recruitment costs, office space, software, bioinformatics access.

Getting started with your application

Email the Implement SWATs team at swats-group@york.ac.uk to check compatibility between the host trial and a proposed SWAT question (See Tables 1 and 2 above). The discussion will also cover advice on processes including support for obtaining ethical approvals, data sharing arrangements, potential project timelines and publications.

Deadline

The deadline for submission of complete applications is: **03rd February 2025 at 1 pm.** Queries relating to this funding scheme can be sent to hrb-tmrn@universityofgalway.ie. All application forms must be submitted as a PDF by email and relevant documentation to hrb-tmrn@universityofgalway.ie by the deadline with '**SWAT AWARD 2025'** in the subject line.

Peer Review Process

Applications will be subject to external peer review. Successful applicants will be notified by 24th February 2025.

Additional Research – optional, and beyond the scope of the funding provided.

While randomised SWATs testing monetary incentives can help us understand whether different strategies are more effective or cost-effective than others, they will not tell us ***why***. The Implement SWATs Team at the University of York is undertaking a process evaluation alongside the SWATs to explore:

- Why specific incentives succeed or fail.
- Which populations respond best.
- What contexts maximise effectiveness.

Teams can join this process evaluation investigating potential ethical issues related to monetary incentives after completing their funded SWAT. Further details of this additional work are available on request.

Additional information

The Implement SWATs team

- Dr Adwoa Parker, University of York (*Chief Investigator*)
- Professor Mike Clarke, Queen's University Belfast (*Programme Mentor*)
- Miss Elizabeth Coleman, University of York (*Statistician*)
- Dr Nassos Gkekas, University of York (*Health Economist*)
- Professor Jeremy Grimshaw, Ottawa Hospital Research Institute, Ontario, Canada (*Programme Mentor*)
- Miss Gloria Mongelli, University of York (*Research Trainee*)
- Mrs Camila Piccolo-Lawrance, University of York (*Trial Support Officer*)
- Professor David Torgerson, University of York (*Programme Mentor*)
- Professor Shaun Treweek, University of Aberdeen (*Programme Mentor*)
- Dr Han-I Wang, University of York (*Health Economist*)

Acknowledgements

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