PRESS Guidance for Researchers Applying for Funding to Conduct High-Priority SWATs of Recruitment and Retention Strategies

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TRIAL FORGE

Contents

Introduction: the PRESS project

This guidance was developed as part of the PRESS project[1] (Protocol and resources development for prioritised recruitment and retention strategies), co-funded by the UK Medical Research Council - National Institute for Health Research Trial Methodology Research Partnership (MRC-NIHR TMRP) and the Health Research Board Trials Methodology Research Network (HRB-TMRN) Ireland. PRESS aimed to develop template SWAT protocols and associated resources to support researchers to replicate high-priority SWATs across multiple trials to strengthen the evidence-base for recruiting and retaining trial participants. The protocols and resources developed as part of the PRESS project can be accessed here.

About this guidance

This guidance document provides example wording to support researchers including a Trial Forge-prioritised SWAT[2], as part of a larger grant application to undertake a randomised controlled trial. The prioritised SWATs focus on randomised SWATs of recruitment and retention strategies.

Various funders support SWATs, including Blood Cancer UK (BCUK), Cancer Research UK (CRUK), Health Research Board (HRB, Republic of Ireland), National Institute for Health and Care Research (NIHR, UK), and Wellcome (UK). While we cannot cover all possible funding application scenarios, this document offers some wording and examples to support researchers with their applications.

This guidance should be used in conjunction with the following linked documents:

- List of priority recruitment and retention SWATs
- PRESS Template Recruitment and Retention SWAT Protocols
- PRESS Statistical Analysis Plan Templates
- PRESS Health Economics Guidance for Undertaking Randomised SWATs of Recruitment and Retention Strategies

How much information should I provide about the SWAT in my grant application?

Each funder and funding stream has its own guidance on including a SWAT, resulting in variations in the required level of detail and type of information. The amount of detail you provide about the SWAT will depend partly on word limits for the overall host trial application and/or the SWAT section. Grant committees will expect the main focus to be on the host trial.

Some funding streams will call for single stage applications, whilst others involve two-stage applications. In single-stage applications, all relevant details should be included for the SWAT - please refer to examples below from HRB and NIHR in Tables 2 and 4, which can be adapted for applications to other funders. For two-stage applications, only brief information about the SWAT may be needed in the preliminary application (Stage One - refer to example below from NIHR in Table 2), with more detail expected in the full application (Stage Two - refer to examples in Tables 2 and 4).

Guidance for including a SWAT in an application to BCUK

BCUK funds SWATs as part of its new call for strategic large-scale clinical trials in the hardest to treat blood cancer[3]. This is a one-stage application, although a one-page EOI is first submitted to BCUK staff for approval prior to opening a full application. BCUK priorities are:

- 'What are the barriers to inclusion and/or non-participation in blood cancer trials?'
- 'How can barriers to trial participation (e.g. social, geographical, financial, communication) be minimised?' The following randomised SWAT protocols and associated resources can be used to address this question:
    - Do cash-based financial incentives increase recruitment of people experiencing socioeconomic disadvantage compared to vouchers with the same face value? (CASH): Study Within A Trial Protocol
    - An evaluation of whether offering flexibility in in-person follow-up visit location increases trial participant retention compared to not offering flexibility (FLEXI): A cluster-randomised Study Within A Trial protocol

- ‘What are the most effective strategies to recruit and engage with underserved and under-represented blood cancer communities to ensure a diverse and representative population is recruited to the trial?’ The following randomised SWAT protocols and associated resources can be used to address this question:
    - Do video(s) providing information about a trial increase recruitment of particular under-served groups important for the trial compared to written information only? (VISUAL): Study Within A Trial Protocol
    - An evaluation of whether using routinely collected data, to shorten a follow-up questionnaire, increases the retention of under-served groups, compared to using a longer, participant-reported questionnaire (SHORT-Q): a Study Within A Trial protocol
    - The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): Study Within A Trial Protocol

Guidance for including a SWAT in an application to CRUK

CRUK funds SWATs as part of its Clinical Research Scheme[4]. This is a two-stage application, with an outline first stage and a second, full application stage. For an example of how much information to include at stages one and two, please refer to Tables 2 and 4.

Table 5 below provides an overview of the CRUK application guidelines, which highlights equality, diversity and inclusivity, methodology, Patient and Public Involvement (PPI), quality of life, and sustainability as particular areas of interest for CRUK. These align with the following priority questions around recruitment and retention:

- ‘What is the most effective way of **involving patients and the public** in trials to improve participant recruitment?’ The associated SWAT protocols are available as: The effectiveness and cost-effectiveness of a trial participant biography on participant recruitment rates (BIOREC): Study Within A Trial protocol
- ‘What is the most effective way of involving **patients and the public** in trials to improve participant retention?’ The associated SWAT protocols are available as: The effectiveness and cost-effectiveness of trial newsletters, co-produced with Patient

and Public Involvement (PPI) partners, on participant retention rates (PPIRET): Study Within A Trial protocol

- What are the most effective strategies to recruit **underserved groups**? The associated SWAT protocols are available as:
    - An evaluation of whether video(s) providing information about a trial increases recruitment of particular under-served groups, important for the trial, compared to written information only (VISUAL): a Study Within A Trial protocol
    - An evaluation of whether cash-based monetary incentives increase trial recruitment of people experiencing socioeconomic disadvantage compared to vouchers (CASH): Study Within A Trial protocol
- 'What is the most effective way of involving patients and the public in trials to improve participant retention?' The associated SWAT protocol is available as: The effectiveness and cost-effectiveness of trial newsletters, co-produced with Patient and Public Involvement (PPI) partners, on participant retention rates (PPIRET): Study Within A Trial protocol

We strongly encourage researchers to consider replications of these SWATs when applying to CRUK. For further information about the rationale and methods, please refer to each SWAT protocol.

Table 5: Clinical Research Scheme Application Guidelines for SWATs, 2024[4]

We encourage SWATs to be embedded into trial applications, particular those evaluating the questions listed here, so that we can collectively generate a body of evidence that can help us overcome common trial challenges more effectively. *SWATs are research sub-studies embedded within a larger clinical trial and are designed to test and evaluate trial processes; optimising the value gained from the host trial by systematically addressing common trial challenges. Many research practices, including recruitment and retention strategies, lack substantial evidence to guide decision making and can have a large impact on the success or failure of a trial. Replication across contexts is key, therefore building a SWAT into a trial doesn't mean that you must start from scratch. Please see the SWAT repository and recent Cochrane Reviews on recruitment and retention for information on existing SWATs that you can replicate within your trial.* *Our areas of interest include, but are not limited to, the following:*

*• **Equality, Diversity and Inclusivity:** for example, investigations into the effectiveness of various activities to improve the recruitment of patients from underserved backgrounds or reducing inequalities in access to cancer interventions.*
*• **Methodology:** for example, investigations into innovative statistical/methodological approaches or decentralisation of clinical trials.*
*• **Public and Patient Involvement (PPI):** for example, investigations into how different PPI approaches promote recruitment.*
*• **Quality of Life:** for example, investigations into complementary therapies or patient reported outcomes measures.*
*• **Sustainability:** for example, investigations into how to reduce the carbon footprint for a given clinical trial/study, or more widely.*

We encourage early career researchers with appropriate expertise to lead these sub-studies, including Clinical Trials Unit staff or Research Nurses, to facilitate career progression. We expect the results of these sub-studies to be published. In addition to these resources, the Trial Forge SWAT Centre at the University of York has set up a Trial Forge SWAT Network to support researchers in the UK and elsewhere in doing SWATs. For further information and advice, please email trial-forge-swat-centre@york.ac.uk

Guidance and examples for including a SWAT in an application to HRB

The HRB funds SWATs as part of larger RCTs applications through its Investigator-Led Clinical Trials (ILCT) Programme[5], formerly known as the Definitive Intervention and Feasibility Awards (DIFA).

Funding is a single stage application process, with up to €20,000 available towards the costs of conducting a SWAT.

Table 3: Health Research Board ILCT Programme guidance notes on methodology sub-studies (including SWATs), 2025

*Applicants are encouraged to include an embedded trial methodology sub-study within their trial proposal. This sub-study may take the form of a Study Within A Trial (SWAT)[5] or other approach focused on improving the design, conduct, analysis, reporting, or dissemination of trials in areas where there is current uncertainty. Please see recently published guidance on how to decide whether a further trial **methodology sub-study** is merited on the particular question[7].*

5.13.1 Are you planning to include a trial methodology sub-study? Y/N

5.13.2 If Yes, provide full details on the following:

- *A clear description of the trial **methodology research question** and its importance.*
- *The **rationale** for the sub-study design (e.g., randomisation, outcomes, feasibility).*

- *Details of the **personnel** involved and their expertise.*
- *Any **power or sample size** calculations, if applicable.*
- *A short **analysis plan** with proposed endpoints or measures of success.*
- ***Inclusion/exclusion criteria** (if different from the main trial).*
- *The **added value** of this sub-study to both the main trial and future trials.*

*Please refer to existing guidance, such as that available from **Trial Forge**, and to the **SWAT Repository Store** (Northern Ireland Network for Trials Methodology Research)[6], to confirm whether a similar methodology question has been addressed previously. Unnecessary duplication should be avoided unless clearly justified.*

***Note**: Trial Methodology sub-studies should be conducted to the same high standard as the main trial (e.g. having a written protocol and plan for dissemination).*

*An additional €20,000 (inclusive of overheads) in funding can be requested for conducting a trial **methodology sub-study**, in addition to the overall budget. The word limit is **750 words.***

Example SWAT application to HRB

This SWAT example below was submitted as part of a larger feasibility trial: *'*Community-based exercise (ComEx Pain) for older adults with chronic musculoskeletal pain: a randomised controlled feasibility trial'[8], led by Professor Karen McCreesh from the University of Limerick, Ireland.

Table 4: Health Research Board ILCT Programme Example SWAT grant application

***Title:** The effectiveness and cost effectiveness of a financial incentive, voucher, for increasing participant retention rates in randomised trials.*

Background

Poor participant retention rates can have adverse consequences on the validity of randomised trials. Financial incentives, consisting of shopping vouchers, is a common strategy used by trial teams to encourage participants to complete follow-up questionnaires, attend follow-up assessment appointments or both. The Cochrane methodology review of strategies to improve retention in trials found financial incentives may improve retention rates compared with no incentive; but the evidence certainty was low (Gillies et al 21) and only three SWATs were included, two that offered voucher incentives. We need more evidence. The Cochrane review and James Lind Alliance retention priority setting exercise (Brundsen et al 2019) both highlighted financial incentives as a priority for evaluation as it would help trial teams to make evidence-informed decisions about whether to use financial incentives, such as vouchers, as an incentive to increase trial retention.

Objectives of this SWAT

1. To evaluate the effectiveness of a €25 gift voucher incentive versus no financial incentive for increasing participant retention rates in a randomised feasibility trial.
2. To evaluate the cost effectiveness of this financial incentive strategy.

Interventions and comparators

Intervention: €25 shopping voucher incentive, given unconditionally before follow-up.
Comparator: No financial incentive.

Allocation method
Randomisation

Outcomes
Primary: *Retention rate, defined as the proportion of participants who complete follow-up data for the host trial, i.e., all post intervention measures including questionnaires.*
Secondary: *1) Cost-effectiveness (cost per participant retained for electronic reminder compared to no reminder); 2) Time to collection of outcome data (days from scheduled date); 3) Number of reminders sent to participants before completion of follow-up assessment.*
Analysis
An 'intention-to-treat' analysis will be performed. Demographic characteristics, including age, sex, and ethnic group (if available), will be presented descriptively as mean (standard deviation) or number (%), as appropriate.
Primary outcome analysis:
Comparison of the questionnaire response rate between the SWAT groups will use logistic regression. The regression model will include the randomised group factor and any SWAT stratification or minimisation factors (e.g., host trial treatment group). The between-groups difference will be presented as number (%) and as both adjusted absolute (i.e., risk difference) and relative (i.e., odds ratio or relative risk) effect estimates, with 95% confidence intervals.
Secondary outcome analysis:
The incremental cost per participant retained will be calculated for the comparisons under evaluation as the difference in costs between the SWAT groups, divided by the difference between groups in completion rates. Direct costs of the retention strategies, and indirect costs associated with administering the strategies and the comparators will be included. The between-groups difference in time taken to collection of outcome data will be analysed using techniques suitable for time to response (event) data such as Kaplan-Meier curves, log-rank test or Cox regression. Time zero will be set as 'day before expected completion date' (equivalent to adding 1 to the time variable to avoid exclusion from the analysis set). For self-report questionnaires, the analysis of questionnaire completeness will be as for the primary outcome.

Impact Statement

The inclusion of the SWAT focused on the effectiveness of financial incentives for participant retention is addressing a key priority in trial methodology research, which will inform future trials on how to best incentivise completion of trial outcomes. Conclusions of this study will be disseminated through the TRMN network.

Guidance and examples for including a SWAT in an application to NIHR

Trial Forge and NIHR have collaborated to provide guidance and examples of wording to include for grant proposals including SWATs, which is available on the NIHR website[9] and outlined in Tables 1 and 2 below. NIHR fund SWATs as part of single stage and two stage applications, and the guidance below covers both scenarios.

Table 1: NIHR Trial Forge Additional Guidance[9]

One way to fill gaps in study process evidence (e.g. on recruitment, retention, monitoring or data collection) is to run methodological sub- studies, or SWATs/SWARs. After a successful pilot conducted in the Health Technology Assessment (HTA) Programme, we are now encouraging applicants to embed methodological sub-studies (up to a maximum funding of £30,000) into applications to the following programmes:

- *Efficacy and Mechanism Evaluation (EME)*
- *Evidence Synthesis (ES)*
- *Health and Social Care Delivery Research (HSDR)*
- *Health Technology Assessment (HTA)*
- *Public Health Research (PHR)*

Building a SWAT/SWAR into a study doesn't mean that you have to develop a SWAT/SWAR intervention from scratch because replication studies (i.e. testing an existing intervention in a different study) are essential to build robust evidence to support decision-making. If you'd like ideas about SWAT interventions, have a look at the SWAT/SWAR repository of SWAT/SWAR protocols. The Cochrane recruitment and Cochrane retention reviews also suggest SWATs that are priorities for replication.

In addition to these resources, the Trial Forge SWAT Centre at the University of York has set up a Trial Forge SWAT Network to support researchers in the UK and elsewhere in doing SWATs/SWARs. For further information, please email trial-forge-swat-centre@york.ac.uk.

Table 2: NIHR Trial Forge Additional Guidance: How much to write on SWATs/SWARs in Stage 1 and 2 proposals[9]

A recurring question raised at SWAT Network meetings has been "How much do we have to write about the SWAT in NIHR Stage 1 and Stage 2 proposals?" Please refer to the following information as guidance.

Stage 1

Words are precious at Stage 1 and committees recognise this. Although extreme, simply flagging that a SWAT/SWAR is planned – "We plan to include a SWAT/SWAR" – would

suffice. There may be committee murmurings about brevity, but the chances of moving on to Stage 2 will not be affected. Despite this, you can expect to be asked for more details if you do progress.

You could, however, do better without spending too many words. For guidance, we have provided two examples, both of which include more than enough SWAT information for a Stage 1 submission, despite both being under 60 words.

Example 1

This example is from a real and successful Stage 1 submission: We plan to include a SWAT to evaluate different approaches of presenting study design to participants during the recruitment process.

Example 2

This example is not from a real submission, but is an example of what you could write: We plan to evaluate a short version of the Patient Information Leaflet (PIL) in a SWAT. We have concerns that a long PIL may be challenging for our participant group and the Trial Forge ID REC8 evidence summary for brief PILs recommends their use only in the context of a SWAT evaluation.

Stage 2

Stage 2 needs more than one sentence. There has to be some detail on the rationale for the SWAT/SWAR, the process targeted and the type of SWAT/SWAR intervention. The intention is to let the committee know in broad terms what is planned, while still recognising that the application will stand or fall on the trial, not the SWAT/SWAR.

Using the previous two Stage 1 examples (the first one from a real submission, the second illustrative), we have provided two examples of what the corresponding Stage 2 text could be. Both examples will give the committees a clear idea of what is proposed, and both are well under 250 words.

Example 1

YTU [York Clinical Trials Unit] has significant experience in undertaking methodological SWATs. The unit has completed and published more than 20 SWATs and has previously undertaken work with the Medical Research Council (PROMETHEUS study) to support collaborative trials units to undertake further SWATs. In this trial we propose to undertake at least two SWATs on recruitment and retention.

For recruitment we will evaluate the effects of presentation of the study design to participants on recruitment rate. Participants will be randomised to receive an infographic (visual document explaining the study) plus the standard patient information sheet (PIS), or just the PIS.

The retention SWAT will use a 2:2 factorial design to simultaneously evaluate the effect of

two retention strategies: a participant newsletter and a thank you card sent in advance of follow up questionnaires. Participants will be randomised to receive:

1. *newsletter and thank you card*
2. *newsletter only*
3. *thank you card only*
4. *neither the newsletter, nor the thank you card*

As is usual with embedded trials, the sample size is constrained by the number of patients approached about the study (recruitment) or actively participating within each host trial (retention), hence a formal power calculation to determine sample size has not been conducted.

The strategies proposed here are either already registered or will be registered prior to implementation on the MRC SWAT repository.

Example 2

Evidence suggests that our participant group is likely to have low literacy. Long written PILs are likely to be off-putting and far less useful than the conversation between recruiter and potential recruit. Short PILs have been tested before (Trial Forge REC8) and demonstrated little effect on recruitment. We think the previous evaluations paid insufficient attention to the content of the short PIL, especially who decided what was on it. We will work with representative public contributors to decide what should be on the short PIL and we will work with our sponsor and ethics committee to ensure our information provision is in line with appropriate governance. Some of our information provision will be explicitly verbal rather than written, in line with HRA guidance on the process of seeking consent.

In line with Trial Forge REC8 recommendations, the evidence base for short PILs is such that they should only be used in the context of a SWAT evaluation, which is what we intend to do. The measured outcomes for the SWAT will be: recruitment, retention, and cost.

Summary

NIHR committees recognise that words are limited and that the main trial needs most of those words. At Stage 1 applicants simply need to flag that a SWAT/SWAR is planned. At Stage 2 a few more details are needed but there is no need to go overboard.

Support with including a prioritised SWAT in your funding application

For support and advice on including a replication of a prioritised SWAT in your funding application, please email trial-forge-swat-centre@york.ac.uk.

Support to undertake monetary incentive SWATs

If you are applying for funding to replicate a monetary incentive SWAT (see MONCENTIVES and CASH SWAT protocols), the Implement SWATs team is running a large programme of coordinated SWATs on this intervention and would be keen to collaborate. If funded, they can provide ongoing methodological support to help ensure the successful delivery of your SWAT.

In return, they ask that you share anonymised SWAT data with them to enable them to update the Cochrane systematic reviews of recruitment and retention strategies. The Implement SWATs team will combine results with similar SWATs in meta-analyses to generate high-certainty evidence on the effectiveness and cost-effectiveness of monetary incentives.

If you are interested, please contact the Implement SWATs Chief Investigator, Dr Adwoa Parker at: swats-group@york.ac.uk

Please share your SWAT findings

If you undertake any of the prioritised SWATs, please share your findings so your results can be included in future updates of the Cochrane systematic reviews of recruitment and retention strategies. Please email Dr Adwoa Parker at: swats-group@york.ac.uk

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