Possible text for ethics submission

[Feel free to use this as you see fit]

Recruiting and retaining participants for randomised trials can be extremely difficult. It is likely that less than 50% of trials meet their recruitment target, or meet their target without extending the length of the trial1-3. Poor recruitment can lead to an underpowered study, which may report clinically relevant effects to be statistically non-significant. A non-significant finding increases the risk that an effective intervention will be abandoned before its true value is established, or that there will be a delay in demonstrating this value while more trials or meta-analyses are done. Underpowered trials also raise an ethical problem: trialists have exposed participants to an intervention with uncertain benefit but may still be unable to determine whether the intervention does more good than harm on completion of the trial. Having recruited participants to a trial, it is essential that they are retained but it is common for 10% or more of participants to be lost to the trial. These participants then provide no data, meaning again that the trial may be underpowered. Moreover, if drop-outs differ between the arms of the trial, a systematic bias is introduced that may undermine confidence in the results of the trial. Finally, poor recruitment and retention can lead to a trial being extended, increasing costs.

Trialists recognise the challenge and use many interventions to improve recruitment and retention but it is generally difficult to predict their effect. The Cochrane systematic review of strategies to improve recruitment4 and the Cochrane review of strategies to improve retention5 both found only a handful of interventions with high quality evidence of benefit. Given how central recruitment and retention are to all trials, it is crucial that more rigorous evaluations of recruitment and retention interventions are done.

One way of doing this is to do a Study Within a Trial, or SWAT6. A SWAT provides a protocol for the evaluation of an intervention to improve some part of the trial process, such as recruitment or retention. This evaluation is then embedded within a host trial, such as [name of trial]. Several teams can follow the same SWAT protocol, meaning the results can be combined in a meta-analysis. This coordinated and collaborative approach means trialists will have faster access to high-quality evidence to inform their trial design, conduct, analysis and reporting decisions.

We would like to make use of SWAT 137 [NB: this SWAT describes a factorial evaluation. If you plan a more straightforward evaluation of brief vs standard PIL it might be better to have a new protocol] in [name of trial], which describes the use of brief Participant Information Leaflets (PILs) to improve recruitment. Brief PILs show some promise as a way of improving recruitment but requires evaluation in more trials before we can conclude that it is effective. Moreover, previous work has found that potential participants consider some information to be crucial (side effects, risks of taking part, practical aspects of taking part) and other information to be less important (who funded the work, insurance cover)8. The most important information (as judged by participants) could be presented in a short PIL, with more information available for those who want it. [insert specific intervention procedures, and details for any planned reviews]. [Describe any ethical consideration and mitigations specific to this SWAT/intervention].

For any type of ethics application consider

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| Why the SWAT/intervention is needed in your trial | -Do you need to do something to help your trial recruit/increase retention?  And/or  -Do you want to add to the evidence base for trial conduct? |

Also consider any possible ethical challenges specific to the SWAT/intervention that you are proposing to use and how you suggest to mitigate these.

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| Potential ethical challenges | Possible response |
| Trial participants are not told that they are randomised in the SWAT (evaluation) | -Offer to include a debrief of the SWAT when providing the trial results.  -Explain that knowledge of the SWAT is likely to change bahaviour and therefore any results will not be reliable and answer the research question/knowledge gap if participants aware of the SWAT. |
| Burden on participants  (both evaluation and implementation) | A brief PIL is likely to be less burden than a longer one. Also, having a brief PIL does not mean a longer version is not available for those who want it. This can be made clear– no participant is being denied information, rather that it is being provided in a layered way. It is unlikely that the SWAT itself will add participant burden. |
| Reviewing progress (evaluation and intervention) | Consider whether there is a need for a review point for the SWAT to decide whether one or other trial process alternative is more promising. This is especially true if the SWAT is being done to actively inform a trial process decision within the host trial, not just for future trials. |

[Disclaimer – these are ethical considerations that the Trial Forge Team could think of when developing this resource pack. Your experience might include other things, please let us know if you think this document needs to be updated]

Our SWAT 137 [or your own protocol] study is part of the Trial Forge initiative to improve trial efficiency (<https://www.trialforge.org>)7.

References

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