The INFORM Structured Grant Form for Trials

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TRIAL FORGE

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This structured grant form is mainly based on two things:

1. INFORM good practice actions. These are broadly divided into Design, Conduct and Knowledge mobilisation. A review of published literature on how to improve trial informativeness (https://onlinelibrary.wiley.com/doi/10.1111/jep.70147), a content analysis of information provided by funders, ethics bodies and regulators (https://onlinelibrary.wiley.com/doi/10.1111/jep.70356), and an interview study with trial stakeholders has led to the choice of items on this form (https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5905842; under review). A description of the mapping that led to the 12 good practice actions is available at https://doi.org/10.1016/j.jclinepi.2026.112274. The whole form is a response to an INFORM Design finding to use existing design tools to support informative trials, see #2 below.

2. SPIRIT protocol reporting guidance (https://www.consort-spirit.org/) and in particular the Trials structured protocol template (https://resource-cms.springernature.com/springer-cms/rest/v1/content/27812550/data/v1). This provides the basic structure of the structured grant form but includes additional INFORM findings.

The form has 34 questions. Each question has a short piece of guidance, which is given here in green. For questions {31} and {32} the guidance text needs funder-specific information to be in line with INFORM. Other questions may also need funder-specific guidance as deemed appropriate by the funder.

While the form captures much of what we have found in INFORM, we recognise that it may not be possible to implement all of it for a variety of reasons. We think each item adds something to the likelihood of a more informative trial, but collectively they will have a much greater impact.

Funders may, of course, have some additional questions linked to funder priorities and policies. At this stage though, we think the questions below are the questions to ask to increase the chance of an informative trial. We recognise, however, that using the whole form in its current form may not be possible. Funders (and others) are free to modify the form in whole or part to fit their processes, but we would appreciate an acknowledgement. We've given a citation suggestion below.

How to cite

The INFORM Structured Grant Form for Trials v1 14/4/2026; [URL to be inserted by us] [insert access date].

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Section 1: Summary

{1} Essential administrative information	
Guidance: Not applicable	
Project title	
Start date	
Duration (months)	
Chief investigator(s)	
Sponsoring organisation(s)	
Overall budget requested	

2} Abstract written for all audiences (plain language)

Guidance: provide a structured, plain language abstract using the headings Objectives; Trial design; Participants; Intervention and comparator; Main outcomes; Randomisation; Numbers to be randomised. Note: these headings are based on the CONSORT standard for trial abstracts: https://www.equator-network.org/reporting-guidelines/consort-abstracts/.

{3} Why is this trial needed now?

Guidance: provide the rationale for why this trial is needed. This should be based on systematic reviews, a formal prioritisation process done by applicant, funder or other organisation, a recommendation from guideline producers, or other evidence-informed justification for the trial.

Section 2: General design

{4} Research question(s)

Guidance: describe the research question in a Participant-Intervention-Comparator-Outcome (PICO) format.

{5} Where will the trial be done?

Guidance: give the settings (e.g., community, secondary care) and locations (e.g., countries, sites, rural, urban) where the trial will be conducted. Explain why these are appropriate.

{6} How will patients or service users be involved in trial design?

Guidance: describe the plans for involving patients, service users, and/or other public contributors in the design of the trial.

Section 3: Participants and sample size

{7} Who will be the participants, and why?

Guidance: describe who the trial participants will be, and why. This should include reference to disease or condition prevalence and severity, i.e., who has something to benefit from improved care. A table of eligibility criteria would be useful, including sociodemographic characteristics (e.g., see https://link.springer.com/article/10.1186/s13063-025-08938-z) and whether these characteristics (e.g., sex, ethnicity) need to be explicitly considered when deciding who should be in the trial. Consider whether eligibility criteria, especially exclusions, may disproportionately affect some groups more than others. Also mention whether other relevant parties such as healthcare staff and patients have been involved in deciding who needs to be in the trial.

{8} How many participants will be needed, and why?

Guidance: describe how the sample size was determined, including all assumptions supporting the sample size calculation. If there are targets within the overall sample (e.g., that at least 45% of participants will be female) describe them here and give the justification.

{9} Who is the person(s) acting as guarantor for the sample size (and statistical analysis more generally)?

Guidance: give the name of the person with competence in trial statistics who acts as guarantor for the calculations described in response to question {8} and the information provided in response to questions {22} to {25}.

Section 4: Intervention and comparator

{10} Describe the intervention and comparator

Guidance: describe the intervention and comparator in sufficient detail to allow replication, including how, when, and by whom they will be administered. Explain the choice of comparator. Describe whether any concomitant care and interventions are allowed or not during the trial. The TIDieR reporting standard (https://www.equator-network.org/reporting-guidelines/tidier/) is a useful framework for this question.

Section 5: Intervention and comparator

{11} What is/are your primary outcome(s)?

Guidance: give the primary outcome(s), including the specific variable being measured (e.g., systolic blood pressure), the analysis metric (e.g., change from baseline, final value, time to event), how this will be summarised (e.g., median, proportion), and time point for each outcome. Describe any measures to ensure data quality.

{12} What other outcomes will you collect?

Guidance: give the secondary outcome(s) and provide the same information as requested for the primary outcome(s) in question {12}. Trial teams often spend substantially more time on secondary outcomes than they do on the primary(s) (see https://link.springer.com/article/10.1186/s13063-022-06973-8) despite few if any secondary outcomes being considered in the sample size justification. Consider whether each of the secondary outcome is essential to answer the research question.

{13} Are there any potential harms?

Guidance: describe how expected and unexpected harms are defined and will be assessed (e.g., systematically, non-systematically). Note whether you will apply any standardised language (e.g., MedDRA). Specify whether you will report all harms recorded in trial publications or only selected harms that meet certain criteria.

{14} How do you know that these are the right outcomes to measure, especially the primary?

Guidance: describe how the outcome choice was made. Describe whose input (e.g., patients, health professionals, managers) was used in this process, either by you or others (e.g., through Core Outcome Sets (COS): https://www.comet-initiative.org/).

{15} When will outcomes be measured?

Guidance: describe the time schedule for participants. This should include when the intervention (including any run-ins and washouts) is delivered, and the timing of visits and outcome assessments. Consider whether the frequency of measurements is justified given the research question and work involved for participants (including staff). A diagram like that by SPIRIT is highly recommended https://www.consort-spirit.org.

Section 5: Treatment allocation

{16} How will participants be allocated to intervention and comparator?

Guidance: describe the trial design (e.g., parallel group, crossover), type of randomisation, allocation ratio, framework (e.g., superiority, equivalence, non-inferiority, exploratory), who will generate the allocation sequence, how allocation will be concealed and who has access to the random allocation sequence.

For questions {16} and {17} it is worth considering how the proposed allocation and blinding approach would score on the relevant parts of a risk of bias assessment tool such as ROBUST-RCT (https://www.bmj.com/content/388/bmj-2024-081199). Some risk of bias problems are easy to fix if caught early (see https://www.bmj.com/content/350/bmj.h809) but greatly undermine confidence in the trial results if left unaddressed.

Section 6: Blinding

{17} Who and how will blinding be achieved?

Guidance: describe who will be blinded, including whether those who assess outcomes are blinded. If blinding is not possible, explain what measures are being taken to protect against bias and ensure the validity of the trial results. Describe when unblinding is permissible.

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Section 7: Recruitment and retention

{19} Who will take informed consent?

Guidance: describe who will obtain informed consent or assent from potential trial participants or authorised proxies, and how.

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Guidance: describe who will obtain informed consent or assent from potential trial participants or authorised proxies, and how.

{20} What retention strategies will you use to ensure you are able to collect outcome data from the number of people given in {8}?

Guidance: describe the trial retention strategies, together with the evidence of effectiveness for these strategies and/or how they will be evaluated. Describe why these strategies will retain the range of participants you identify in response to question {7}.

{21} How has the feasibility of your proposed recruitment and retention strategies been discussed or tested with people such as health professionals and potential trial participants (i.e., those listed in {7})?

Guidance: describe how the approach to recruitment and retention has been discussed and tested together with those needed to make the trial feasible. These individuals could include potential trial participants (i.e., patient and public involvement), health professionals, managers etc. Provide data from feasibility and other work that demonstrate that the trial will deliver the required number and range of participants within a study of the duration given in response to question {1}.

Section 8: Analysis

{22} What are the statistical methods you will use for the primary and secondary outcomes?

Guidance: describe the statistical methods that will be used to compare groups for primary and secondary outcomes. Describe who will be included in each analysis (e.g., all randomised participants).

{23} How will missing data be handled?

Guidance: describe how missing data will be handled. Justify the chosen techniques.

{24} Are there any additional analyses?

Guidance: describe any additional analyses such as subgroup analyses. Describe any subgroup analyses you need to consider for participant subgroups (e.g., sex, socioeconomic status) identified in response to question {7}.

{25} Will there be an interim analysis?

Guidance: describe any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial.

Section 9: Oversight

{26} How will ethical and other approvals be obtained?

Guidance: describe plans for seeking research ethics committee/institutional review board (REC/IRB) and other approvals.

{27} Protocol Amendments: future adaptability and technological evolution

Guidance: describe any anticipated areas in which the intervention, comparator, or methods may evolve during the study (e.g., changes in technology, standard of care, or societal practice), and outline the mechanisms for assessing and, if appropriate, adapting the trial protocol to maintain scientific and ethical relevance.

{28} How will the trial be managed day-to-day?

Guidance: describe the group that will run the trial day-to-day, and which will provide organisational support to trial sites. Describe the composition, roles and responsibilities of those tasked with day-to-day management, how often they will meet, and how trial progress is monitored, and correcting actions taken.

{29} What external oversight with the trial have?

Guidance: describe the external committees that will have oversight of the trial. These are likely to include a Trial Steering Committee and a Data Monitoring and Ethics Committee but there may be others depending on the nature of the trial.

Section 10: Training

{30} What are the arrangements for training during the trial?

Guidance: describe the training that will be provided to those involved in recruitment, retention and data collection. Describe how training needs will be monitored throughout the trial and updated as needed. Note: Good Clinical Practice is taken as a given; this section is about additional, more targeted trial-specific training.

Section 11: Dissemination

{31} Name the trial registry you will use to register the trial

Guidance: give the name of the trial registry in which the trial will be registered. The registry should be on the WHO International Clinical Trials Registry Platform (https://www.who.int/tools/clinical-trials-registry-platform/network, or clinicaltrials.gov (https://clinicaltrials.gov/).

Note that trial registration is a condition of funding and will be checked at month [x as per funder policy] by the funder.

{32} How will the results be disseminated to participants, healthcare professionals, the public and others?

Guidance: describe plans to share the trial results with participants, healthcare professionals, the public and others. The results should be published within [x] months of [end of grant as per funder policy] and put onto the trial registry named in {31} where the registry supports it.

Section 12: Data sharing

{33} How will the trial data be made available?

Guidance: describe plans to share the participant data, including the data dictionary, statistical code and other relevant materials to enable others to examine the data behind the trial results.

Section 13: Competing interests

{34} Are there any competing interests?

Guidance: describe and actual or possible financial and other conflicts of interest for principal investigators and members of oversight committees.