

Note: the numbers in square brackets ({x}) are references to question numbers on the INFORM structured grant form
(https://www.trialforge.org/structured_grant_form/).

Question 1

Describe the study design and how data will be collected.

In your description include the following where relevant to your research:

- the study design (for example, experimental, observational, qualitative, or mixed-methods approaches such as randomised controlled trials, cohort studies, or ethnographic studies) {16}, including relevant data collection methods (for example semi-structured interviews or focus groups) {15}
- how participants will be allocated to study groups and the methods you will use to minimise or protect against bias, including blinding if appropriate {16, 17}
- the type, frequency, duration, and timing of all data-collection activities in your research (for example, interviews, focus groups, surveys, participant-observation sessions, physiological or digital data collection) {10}
- the primary and secondary outcomes {11, 12} and rationale for their selection {14}
- the locations (e.g. countries, sites) and settings (e.g. community, secondary care) of the research involving human participants and why these are appropriate {5}
- the form, frequency and duration of planned follow-up including any long-term follow-up or respondent care plans {10}

If your research includes a clinical trial, we recommend uploading an additional figure, such as the [SPIRIT-style figure](#), to clearly show the timeline of participant enrolment, interventions, and assessments. {15}

Maximum 800 words.

Question 2

Does your research include a health intervention?

We use the term 'health intervention' to cover a wide range of interventions from vaccines and drugs, through to digital and behavioural interventions, that support the diagnosis, treatment or prevention of diseases or a health condition.

If 'Yes' is selected:

Describe the health intervention.

In your description, include the following where relevant to your research:

- the type, frequency, duration, and timing of the intervention and comparator {10}
- how, when, and by whom each intervention and comparator will be delivered {10}
- the justification for the chosen comparator for answering the research question {10}
- whether participants may continue to receive other care or interventions during the study, and the rationale for allowing or restricting such concomitant care {10}
- how expected and unexpected harms are defined and will be assessed {13}

Maximum 300 words.

Question 3

Describe who the participants in your research will be. Explain why they are the appropriate population for the research.

In your description include the following where relevant to your research:

- the main inclusion or exclusion criteria and clear justification for these {7}
- the number of participants (or respondents/ethnographic subjects) in each group {8}
- the expected sociodemographic characteristics of the sample, and how you will consider or account for sex, gender or both, where relevant. {7}

This includes the use of tissues and cells. If you do not know the sex of the sample (s), describe how you will determine the sex. If you plan to use single-cell or single-gender, you should explain why. Read our [sex and gender in health research policy](#)

Maximum 300 words.

Question 4

Describe how you will analyse each study data set.

In your description, include the following where relevant to your research:

- a sample size justification, including assumptions used in any power or sample size calculations {8}
- who will be included in each analysis {22}
- the analysis technique(s) that will be used and the justification for its use to answer the research question {22}
- how missing data will be handled with a justification for the technique chosen {23}
- any planned sub-group or interim analyses {24}
- who acts as guarantor for the statistical analysis and sample size {9}

Maximum 250 words.

Question 5

Describe your strategies for recruiting and retaining participants in your research.

In your description, include the following where relevant to your research:

- the evidence supporting these strategies, and how you will monitor and evaluate their effectiveness throughout the research {18,20}
- how these strategies take into consideration potential circumstances of political instability or insecurity or national/international emergencies during the project
- how your proposed recruitment and retention approaches have been developed, discussed, or tested with the people and groups essential to feasibility, describing and justifying the expected rate of recruitment) {21}
- Say who will take consent, when and how {19}

If your research includes a clinical trial, you must also tell us:

- how you will comply with our policy on ensuring the inclusion of under-served groups and {7}
- how your recruitment and retention methods will engage with under-served groups {7}

Maximum 350 words.