



Clinical Study Guidelines (Observational)

Please provide a brief description of your observational clinical study, based on the headings below:

1. Study design

Describe the study design proposed.

2. Study population

Describe the inclusion and exclusion criteria. Include details of the source of the study population – for example, is the population a random sample from the larger population or are study participants obtained from a disease register?

3. Including a representative study population and recruiting people from under-served groups

Describe the demographics of the population that is affected by the condition being studied (e.g. age, sex/gender, ethnicity). Explain how you aim to recruit a diverse group of participants that represent the relevant population, including underserved groups (see [NIHR guidance](#) on defining and including under-served groups).

4. Measures of exposure

Describe the main exposures of interest and how they will be assessed if appropriate.

5. Confounding factors

Describe the main anticipated confounding factors, how they will be measured and any proposed adjustment for confounders.

6. Outcome measures

Describe primary and secondary outcomes measures. Explain how outcomes will be measured.

7. Follow-up

Provide details of frequency and duration of follow up.

8. Proposed sample size

Specify the number of participants and centres in the case of multi-centre studies.

9. Power calculations

Give details of the estimated effect size, power and/or precision employed in the calculation. Justify the estimated effect size and the assumptions underlying the sample size calculations.

10. Loss to follow up

Provide details of any anticipated loss to follow up and explain how these will be dealt with.

11. Planned subgroup analysis

Describe any planned subgroup analysis, including any sex/gender stratified analysis. If you are not planning to perform a sex/gender stratified analysis, please justify why not.

12. Bias

Identify potential sources of bias and explain the methods used for protecting against such bias.

13. Statistical analysis

State the purpose, proposed type and frequency of any statistical analyses, including the selection of participants to be included in the analyses.

14. Data access

Describe the data access arrangements.

15. Data and sample storage

Describe the processes for data and sample storage and archiving.

16. Flow diagram

Please include a flow diagram (single-side of A4) for submission with your application form. This should illustrate the study design and the flow of participants.

17. Project timetable including recruitment rate

- Describe how recruitment will be organised, the time period over which it will take place, and evidence that the planned recruitment rate is achievable.
- Please include the following information:
 - the process for identifying potentially eligible participants
 - the proportion of potentially eligible participants who will fulfil the inclusion/exclusion criteria
 - estimated consent rates
 - details of ongoing studies that are competing for the same group of participants or whose results may affect recruitment
 - results of any pilot study indicating that planned recruitment targets can be achieved.
- Provide a timeline for the study.