This document shows and example of a task sheet used by writing groups to draft best practice principles for the PeRSEVERE project. More details about this are available at https://perseverepprinciples.org/how-we-developed-the-persevere-principles/.

Topic area:

- **Trial design and protocol**: how should we design trial processes to mitigate the effects on trial data collection of participants' decisions to stop some or all elements of trial participation?

Task

- Agree principles relevant to the above area. Aim to reach a point where you feel they are ready for further dissemination.
- Principles should be:
    - As simple as they can be; as broad as they need to be
    - In clear language and understandable by non-trialists where possible
    - Specific to the topic (suggestions for other topic areas are welcome and we can cross-check against those groups' suggestions later)
- There is no minimum or maximum number of principles, but it's possible that a small number of clear, broad principles would be easier to share and discuss further.
- Consider if any of your principles might be more important than others, or whether you need to add any caveats.
- In the table provided, also add a justification or explanation for each principle. This will explain your thinking, help us explain the principle to others later on, and also inform write-up of the related publication.
- There is no word limit to any of this, though being concise is usually helpful.

Record your principles in the table on page 2, and collaborate within this document through Microsoft Teams.

Items/subjects to consider

Based on previous work at the CTRU in Leeds and on discussion at the meeting on 31st October (see discussion sheets available in Teams), the following are points you might consider covering:

- Flexibility of trial follow-up schedules, including data from different sources
- Burden of trial follow-up schedules
- Designing follow-up to cope with people moving house
- Consider alternative trial design if predict lots of people will not complete planned follow-up schedule
- Amount of data collected
- Trial-specific definitions
- Protocol instructions for handling end of follow-up events (i.e. when participants want to stop in some or all parts of a trial, or lose contact with the trial)
- Incentives/reimbursement/funding (e.g in relation to continuing data collection after a decision to stop follow-up or treatment)
- Sample size inflation
- Explain importance of follow-up in protocols

- Risks of putting too many follow-up options in protocol (e.g. risks of introducing bias; risks of 'encouraging' stopping follow-up)

Proposed principle	Explanation & justification