PeRSEVERE: PRincipleS for handling end of participation EVEnts in clinical trials REsearch – Key Messages

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PeRSEVERE collaborative group*

This document gives a short summary of the PeRSEVERE principles, which guide how to prepare and run research studies given that some participants will stop, reduce or change their participation before their participation was originally due to end.

This document is only intended to serve as an introduction to the principles. We encourage anyone interested to review the full Principles and Explanation document, available here: https://ukcrc-ctu.org.uk/page-persevere/

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Overarching principles (O)

- Everyone running or taking part in studies should be aware that participants may choose to change, reduce or stop their participation after they agree to join the study (principle **O1**).
- The nature and extent of participation changes should be the participant's decision to make, within the limits of what is possible for a given study. Their decision should be informed and freely-given (principle **O2**).
- Everyone running or taking part in studies should be aware that collecting as much as possible of a study's planned data can help a study reach a clear and reliable conclusion (principle **O3**).
- Loss of contact between a participant and researchers should not be considered the same as a participant saying that they want to stop study participation (principle **O4**).
- Study data collection should continue until a study participant explicitly tells researchers that they want it to stop (principle **O5**).
- Data collected for a study up to the point a study participant stops providing data should be used in the study analysis, and kept with the other study data until the study is over (principle **O6**).
- Stopping participation early does not affect participants' right to receive study-related information later on, if they want to receive it or if it could be important for them to have (principle **O7**).

Study Development and Participant Information (D)

- Studies should be designed and resourced to allow data collection to continue wherever possible, particularly for study outcome data (principle **D1**).
- Study protocols should include clear instructions on how participation changes should be practically managed (principle **D2**).
- Before participants agree to take part in a study, they should receive clear and balanced information about what will happen if they want to stop participating (principle **D3**).
- Participants should be informed, before they consent to join a study, about what will happen if contact is lost during the study (principle **D4**).
- Throughout each study, researchers should make reasonable efforts to check that participants are still willing and able to take part. Researchers should be prepared to discuss possible changes to participation, where these might allow participants who are still willing to make a contribution to the study to do so (principle **D5**).
- Everyone involved in running studies should be trained and supported to manage participation changes for the good of both the participants and the study (principle **D6**).

Data Management and Monitoring (M)

- Data about study participation changes should be recorded in a standardised way and include enough detail to usefully inform study management, analysis and reporting (principle **M1**).
- All those responsible for running and overseeing a study should, at appropriately regular intervals, review summarised data about participation changes in the study (principle **M2**).

Study Analysis and Reporting (R)

- When participation changes mean that not all the study data has been collected as planned, researchers should analyse the study in ways that give the best chance that the study will still have reliable results (principle **R1**).
- End of study reporting of participation changes should be done consistently within a study, showing any changes in level of participation, preferably split by treatment group (principle **R2**).