

This document records the agreed approaches to handling feedback on draft PeRSEVERE principles. More information about this is available at <https://perseverepinciples.org/how-we-developed-the-persevere-principles/>.

Aims:

- The draft PerSEVERE principles were sent out for feedback during June 2020 and more than 300 comments have come back in response. We will soon start the process of seeking potentially a lot more feedback. We therefore should make sure we deal with all feedback in a consistent and transparent way.

Suggested feedback handling process:

- Feedback will be collected in a standard way, e.g. in an Excel spreadsheet with the same columns. This doesn't mean the feedback has to be *provided* in this way, but if it is provided in a different way then it will be added to the same format.
- Each principle's leads will review the feedback, consulting with the wider principle working group and/or the PerSEVERE steering group (including the patient group), as required.
- There will be a set list of possible responses to each piece of feedback:
 1. Amend principle [with details of suggested change]
 2. Amend explanation text or other considerations [with details of suggested change]
 3. Amend implementation guidance [about *how* the principle should be put into practice – with suggested change]
 4. Discuss with principle working group [temporary category – after discussion it will be clearer whether amendment required or not]
 5. Discuss with steering group [also temporary as above]
 6. Agree with comment but no change required
 7. Disagree with comment [with space to explain; e.g. comment is re-raising an issue that has already been discussed extensively and agreed before]
 8. Note consideration for now [temporary – e.g. if lots of the same comment then may consider amendment, but a single comment then maybe not]
 9. Other response [with space to explain]

Conservative approach to amending principles?

- We may want to be wary of continually updating principles in response to new feedback, as this could result in a lot of changes (and maybe gives too much weight to new feedback, when the most up-to-date principles should already reflect all the feedback given so far).
- Therefore when considering an update to the principle text, we might think about:
 - o Is the suggested change in scope of PerSEVERE?
 - o Might the change make the principle too long? Fundamental points must of course be included, but consider whether it might be possible to reduce words elsewhere, or split the principle up.
 - o Has the issue being raised already been discussed and a position agreed?

- Is it high-level enough? The PeRSEVERE principles are generally high-level, about *what* should happen rather than *how* it should happen. The ‘how’ should go with the implementation guidance rather than principle text.
- Is a change actually being suggested by the commenter? In some cases they might be talking about a specific related issue, while not actually disagreeing with the fundamental principle message.
 - For example, for the principle that we should retain data collected until the point a participant stops taking part in a trial, a comment might say that it’s already in the UK Data Protection Act 2018 that this can happen. They are right, but they aren’t actually disagreeing with the principle. These sorts of comments can and should be taken on board when thinking about the explanation text and the implementation guidance.