

Dear Sirs,

The document as a whole is comprehensive and welcomed. The emphasis on proportionality is especially sound. It would be burdensome for a small trial to undertake the breadth of measures that would be sensible for a mass or longitudinal study.

I note that within the document there is no reference to the structure of the management team. Whilst it is reasonable to conclude that the team would consist of members experienced, interested, committed and of value to the objective, easily dismissed from such a team, yet of equal value, is the contribution made by PPI. I would like to see within this document that the elements of risk be assessed and advised by the inclusion of PPI.

Whilst scientists, medics and data specialist may be capable of conducting a risk assessment, there are elements and components that contribute to risk that only PPI might spot.

Neither is there any mention of an ethics committee, which while being mandatory, has a place within the setting and context of this paper.

The above can be directly published with my personal/organisation information (I consent to publication of all information in my contribution in whole or in part including my name/the name of my organisation, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).

I am a lone individual interested in supporting research. I represent nobody else nor any other organisation. I was informed of the request for contributions via an email sent me from the NIHR.

Should any clarification be necessary I can be reached on this email.

Very best wishes,

Jeremy