**Reviewer’s report**

**Title:** Research involving adults lacking capacity to consent: a content analysis of participant information sheets for consultees and legal representatives in England and Wales

**Version:** 0  **Date:** 25 Oct 2018

**Reviewer:** Seonaidh Cotton

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I found this a very interesting and useful paper.

The authors selected studies to include on the basis of capacity status (no prior capacity, progressive loss of capacity, sudden/acute loss of capacity), and also categorise studies into CTIMP or non-CTIMP type studies. Is it possible to include additional reflection on any similarities or differences in the key themes between these types of study?

There is discussion of the consent form (starting line 272) - I wondered whether term "consent form" should be modified as the proxy is not giving consent, but being consulted.

The authors are very clear that frame of reference is legislation governing research involving adults lacking capacity in England and Wales. The legislation differs in Scotland, and it would be helpful for the authors to clarify that the PILs included in the review were those written for recruitment in England and Wales and not for recruitment in Scotland. If any of the PILs were aimed at recruitment in Scotland, then some of the terminology around "consent" may have arisen from PILs written for studies recruiting in Scotland. In additional file 1, the recruiting countries are listed as UK/EU/Other - given the differing legislation and terminology, the authors may wish to consider listing England/Wales and Scotland separately in this table. Furthermore, the authors may wish to reflect on where the lead investigators were based (England/Wales or Scotland) as this may have influenced the terminology included in the PILs.

The authors present some examples of text describing how the proxy might approach decision making in table 3. Would they go as far as recommending some of these phrases as examples of good practice that others could utilise when developing PILs.

On lines 362-364, the authors note that there is no template for clinical trials falling under the CTR - again, would they go further in recommending that such a template be developed (and if so, who should take responsibility for this?). They make a similar point on line 446, noting that further guidance is needed.
The authors make an important point on line 444/445 about not increasing the length of study documentation. They may wish to consider the potential for a layered approach to providing this type of information.

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