Reviewer’s report

Title: Actors involved in the regulation of clinical research: comparison of Finland to England, Canada and the USA

Version: 1 Date: 3 March 2015

Reviewer: Iris Pasternack

Reviewer’s report:

- Major Compulsory Revisions

Abstract

Abstract, background
1. The current content is actually objective. Please describe background: i.e. observed differences/conflicts, motivations for this study.

Abstract, methods
2. The last sentence is vague. Please consider providing more specific information on methods.

Abstract, results:
3. “pure trials” is probably not a standard term. Please consider revising.
4. “variety of business”. Unclear what is meant with these.

Background
1st paragraph
5. “the regulation industry” is not a well known concept. Please explain or revise.
6. The last sentence is complex and difficult to read.

2nd paragraph
7. The reader is curious to know why Finland is selected as the target. Please add something about the motivations of this paper.

3rd paragraph
8. What is the difference between national and public in this paper? Please be explicit with the terms.

Methods
9. I think the methods section should include the basic assumptions or at least the anticipated categories where similarities and differences occur. The methods section should present the problems and the framework for data collection. The informations sources and data collection are well described.

1st paragraph
10. “systematically collected”. Please provide more information of what is meant by ‘systematically’ in here. Earlier it was mentioned that convenience samples
were used, which is in contradiction to this.
6th paragraph
11. “a theoretical framework was created”. Please describe in more detail this framework
Results
12. The authors use past tense, but I recommend considering present tense, for readability.
1st paragraph
13. “welfare state” not a standard term, confusing in this context
2nd paragraph
14. “...state-organized services, while private services.” Do you mean “...state-organized services, in which private services...”
15. The last sentence is unclear. Please provide some further clarification.
4th paragraph
16. “The number of...trials...was high....”. This leaves the reader without knowledge of ‘how high?’ or ‘high compared to what’. Please elaborate.
17. “ordinary health services” not a standard term. Please clarify or revise.
10th paragraph
18. “arms-length agency” is understandable for many but I think it should be defined here.
19. What is meant by “spill over effects”, please clarify, provide example.
12th paragraph
20. “...to avoid the related problems”. It is unclear which problems are meant.
13th paragraph
21. “In Finland and Canada, regulation and research facilitation were often intermingled at personal level.” This sentence is hard to understand, please modify and/or provide example.
14th paragraph
22. “...permission for research was usually a formality, ...” Please define what is meant by formality in this context.
- Minor Essential Revisions
23. There is the personal “I” in several places in the midst of the general passive voice in the text. I suggest keeping the passive voice here too.
Methods
8th paragraph
24. The terms could be better presented in table format
- Discretionary Revisions
Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests