Author's response to reviews

Title: Research ethics committees: agents of research policy?

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Author's response to reviews: see over
Dear Editors
Enclosed is a revised version of my paper "Research ethics committees: agents of research policy?". Below is the list the changes I made according to the referee comments. If further changes are needed, please let me know.
Yours sincerely
Elina Hemminki

(The numbering is mine)

Comments by Iain Chalmers
1) Redraft the paper as a shorter commentary. I have now abbreviated the paper, reorganized the text and corrected it to suit as a commentary using subheadings.
2) "Subjects "should be "participants". Done.
3) Check the manuscript by a native English speaker. A native speaker has now rechecked the paper.
4) Additional references. I have now added some new references (thank you for the suggestions)

Comments by Paul Wainwright
1) The objective as stated in the Abstract is to analyze in the light of EU directive. The text has been changed throughout, including the abstract, to place less emphasis on the EU directive.
2) We really need better access to data. I chose the suggestion of the other referee to shorten the paper and make it a Commentary rather than a research paper. Thus, addition of more details has not been made.
3) page 6, human integrity in the Finnish law The Finnish law defines medical research as such research which interferes with "koskemattomuus" (immunity; integrity) of human, fetal or embryo; both psychic and physic integrity is covered. It is unclear terminology and one of my arguments is that the law arbitrarily defines medical research.
4) Informed consent in drug but not in the other trials. I have now clarified the text when it concerns Finnish and when EU regulation, as well as made it clear that the in the Finnish law not asking informed consent is an exemption.
5) The final paragraph on page 7...nothing in particular to do with the EU directive...Explicit evidence. I have now deleted EU-directive from this paragraph. For details, see my answer to comment 2.
6) Informed consent for treatments in common use. The points on this issue are now organized as a separate chapter under the heading "Double standards on informed consent to treatment" to make the message clearer. I am not talking about old interventions on new indications but old treatments for old indications, i.e. on comparing two or more treatments already in use.
6) The first example of the possible unintended consequences. This chapter is now reorganized and the old heading deleted. The first example is now part of the Informed consent for treatments in common use and hopefully is clearer in this context.
7) The second objection is now rewritten to make it clearer.
8) The EU directive does not work so well for complex designs. I have now modified the text to make it clearer that it is not the EU directive itself but when it and other codes made to
accommodate the needs of drug trials have been integrated to the Finnish law, problems have arisen.

9) *The fourth complaint does not add anything useful.* I have now combined this to the modified "second complaint".

10) *The fifth complaint.* This paragraph is now transferred to another place and modified. Furthermore, I have deleted the word "collegial" because it was misleading in regard to independence.

11) *Page 11 typo* has been corrected.

12) *The responsibility back to researchers.* I have now reorganized and modified the text to make the work division between the different partners clearer.

13) *The Pages 12 and 13 make various assertions but not well argued.* I have now rewritten and abbreviated pages 12-14. The patient leaflet question has been transferred to the section of "Regulation" describing the current situation.