Reviewer's report

Title: Development of a survey on the regulatory requirements for clinical research in the EU by the European Clinical Research Infrastructures Network (ECRIN) and suggestions for a clinical research classification

Version: 1 Date: 31 May 2009

Reviewer: Joel Lexchin

Reviewer's report:

This article is a description of the problems associated with the development of an European survey about clinical research. My main issue with the manuscript as it stands is that there are a number of areas where more information is required. I have provided examples below where I feel that more explanation is necessary for the general reader to fully understand the context in which the survey was undertaken.

Major Compulsory Revisions

Page 6, second paragraph:
Provide more details about ECRIN - which countries are part of it, do people participate as individuals or as representatives of national governments, etc.

Page 7, first paragraph:
Give more details about Directive 2001/20/EC

Page 8, first paragraph:
What does the term “correspondent” mean? Also are the 10 countries listed all of the members of ECRIN?

Page 9, second paragraph:
Please give some examples of definitions that need to be merged.

Page 9, third paragraph:
How was the survey distributed – by post, by e mail, web based, etc.? Were nonrespondents contacted, if so by phone, e mail, etc., how many times were they contacted?

Page 11, first paragraph:
How were the main topics of the ECRIN survey decided upon? The Methods section describes how the categories of clinical research were chosen but not how the topics were selected.
Level of interest: An article whose findings are important to those with closely related research interests

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