Reviewer’s report

Title: The Best Interests of the Child and the Return of Research Results: International Comparative Perspectives

Version: 2

Date: 12 June 2014

Reviewer: Adriana Ceci

Reviewer’s report:

- Major Compulsory Revisions

1- First of all the Authors should clarify if the article focuses essentially on genetic research, as suggested both in the summary (background section) and in the conclusions, or more in general to paediatric research. If genetic research is the focus of the paper, this should be specified since the beginning (in the title), and the regulatory framework related to this field should be better developed (references to legal texts and guidelines need to be implemented). If genetic/genomic research in paediatrics is only a part of the analysis, the paragraph related to this type of research should be better identified and developed (see point 5 below).

2- Due to the focus of the paper, the large legislative and regulatory framework dealing with rights and protection of paediatric patients included in clinical trials and other studies should be mentioned and discussed (please refer to ICH Topic E11 guideline – 2000 - applicable at international level, the FDA paediatric rules and in particular in Europe the CT Directive 2001/20/EC, as well as the Ethical Recommendations issued by the EU Commission in 2008 in which several topics considered in this manuscript are taken into account).

3- The meaning of ‘return of research results’ is unclear. For a valid understanding of the text, this aspect should be elucidated.

4- The methodology of the work (sources of data, period of data collection, countries included into the analysis, method for comparison, etc) is not detailed.

- Minor Essential Revisions

5- The manuscript makes several references to ‘genomic research’, even at the very beginning. However, this issue seems not well-addressed. The regulatory framework on this topic is quite different from other paediatric research and it is not mentioned in the results and discussion.

6- The article does not mention the conditions required to carried out a genetic test in children according to the principle of the best interest of the child: e.g. see French legislation (art. R. 1131-5, al. 3 and art. R.1131-4 al.3). These requirements are the essential pre-conditions to be assessed in order to carry out genetic tests (even in the framework of research), that could help to justify the
necessity to communicate research results

7- The legal references related to the legal context in France are not correct, the paragraph should be revised: e.g. the obligations to communicate global results of research as well as results related to the health of person are provided in article CSP L1122-1 (coming from the law 2004-806) and not in Loi jarde, as mentioned. Furthermore, the reference to art. L1131-1-1 does not refer to the secondary genetic research

- Discretionary Revisions

8- I suggest to revise the paper, in order to better detail at least main objectives, methods, definition of the context and conclusions.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**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.