Reviewer's report

Title: Environmental health and justice and the right to research: institutional review board denials of community-based chemical biomonitoring of breast milk

Version: 1
Date: 8 September 2015

Reviewer: Susan M. Pinney

Reviewer's report:


The historical review of the events surrounding the effort to obtain IRB approval for the Breast Milk Pilot Study, the data collected by the researchers, and the discussion in this manuscript provide a synopsis of very important issues and barriers encountered by this research team. An important story to be told, well written and flows very nicely.

I assume that this manuscript was submitted as a case report, since the GUIDELINES in the email describe the criteria for a case report in Environmental Health. That said, the manuscript seems to exceed the word limitation for a case report, although I could not do a word count with the pdf file.

Major Compulsory Revisions:
None

Minor Essential Revisions:
1. Although very interesting, the manuscript is long. Please try to tighten it a bit, especially in the text before the Discussion section. The analysis of the challenges, as presented in the Discussion section, is excellent.
2. At some places it is not clear whether the IRB rejected the entire proposal or just portions of the plan, especially in the paragraph right before Research Ethics Hierarchy.
3. Please describe “participatory action research”, a term that is not as frequently used as “community based participatory research”.
4. Much of the interaction with the Alaska Area Institutional Review Board seemed to stem from differences in the assessment of risk/benefit of reporting results of breast milk biomonitoring. Please add to the discussion some thoughts on how one would assess risks versus benefits. Are there any situations in breast milk biomonitoring where the risks of reporting back may outweigh the benefits? What is the appropriate intervention in situations where the level of an environmental chemical in breast milk is such that the risk of continuing breast feeding may outweigh the benefits?
5. Many acronyms are used in the text, so many that it became difficult to read. Then I discovered the list of acronyms after the Conclusions. Please move to the
beginning of the article!

Discretionary Revisions:

6. IRB denial of a study that includes reporting back individual biomonitoring results is not limited to studies conducted in indigenous communities. Many researchers across this USA have experienced this action by the IRB. Most elect to just eliminate that portion of their research plan. Could you generalize some of your discussion and conclusions to research settings that are not in indigenous communities?

Minor issues not for publication:

Sentence structure and punctuation (especially the use of colons) are lacking in some portions of the manuscript, which would benefit another pass at editing. For example, the results section of the abstract should be written in the past tense.

**Level of interest:** An article of outstanding merit and interest in its field

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

**Declaration of competing interests:**

I declare that I have no competing interests