Reviewer’s report

Title: An architecture and method of operation for improving the protection of privacy and confidentiality in population-based disease registers.

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Reviewer: Dr Greg E Simon

Level of interest: A paper whose findings are important to those with closely related research interests

Advice on publication: Accept after discretionary revisions

I have a few specific suggestions:

1) The authors might more clearly describe which of the various roles entities already exist, which roles might be served by existing organizations, and which would require creation of new organizations or entities. For example: Health care entities and disease-specific registries already exist while population registers and identifier translation agencies do not. Could these two roles be filled by existing entities? Why or why not?

2) The authors might clarify how the proposed structure would relate to existing ethical review committees or institutional review boards. Would the proposed privacy and confidentiality protection committees replace or supplement existing ethical review processes?

3) The authors might discuss how patients might express preferences and provide consent at the time original data collection. For example: would patients be allowed the option of “opting out” of all research use?

4) How would such an infrastructure be funded? Should research organizations be expected to contribute to the support and maintenance of such a system. Since initial fixed costs would be relatively high compared to ongoing maintenance or marginal costs, what funding mechanism would support initial development?

Competing interests:

None declared.