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Response to Open Peer Commentaries on “Genomic Inheritances: Disclosing Individual Research Results From Whole-Exome Sequencing to Deceased Participants’ Relatives”

Sara Chandros Hull,

National Human Genome Research Institute

Ben Chan,

Lawrence University

Leslie G. Biesecker, and

National Human Genome Research Institute

Benjamin E. Berkman

National Human Genome Research Institute

We are grateful for the substantive analyses that the open peer commentaries contributed to our target article on returning genomic results to families of deceased participants (Chan et al. 2012). A prominent theme in the commentaries was the call to develop criteria for classifying results to enable prioritization in disclosure. We agree. The commentators raised a range of important goals that should be furthered by the research community as it develops such criteria:

1. Highlighting results that fall under a positive duty to warn, which a passive disclosure policy would fail to meet (Bombard et al. 2012).
2. Enhancing the quality of disclosure, e.g., in terms of timeliness and intelligibility, so as to maximize benefit to relatives (Costain and Bassett 2012; Fullerton et al. 2012; Johnson et al. 2012).
3. Enhancing the consent process, for example, by discerning those classes of results that raise privacy concerns (Bredenoord and van Delden 2012; Galvin and Clayman 2012).
4. Facilitating the design of disclosure plans that are tailored to the population, duration, and analytic targets of a particular study (Blasimme et al. 2012; Johnson et al. 2012).

The commentary submitted by Mark Rothstein (2012) warrants a more detailed response. Our analysis was not “NIH policy,” as he states in the final paragraph of his commentary,

Address correspondence to Ben Chan, Main Hall, Lawrence University, Appleton, WI 54911, USA. benchan@alum.swarthmore.edu.

This correspondence piece is a response to the Open Peer Commentaries on “Genomic Inheritances: Disclosing Individual Research Results From Whole-Exome Sequencing to Deceased Participants’ Relatives,” by Ben Chan, Flavia M. Facio, Haley Eidem, Sara Chandros Hull, Leslie G. Biesecker, and Benjamin E. Berkman, which appeared in *American Journal of Bioethics* 12(10), pp. 1–8.

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but rather an approach taken by one research group in the context of a specific study. Although many of us are NIH employees, we are not authorized to set NIH policy, and our views do not necessarily reflect the official views of the NIH.

In contrast to Mr. Rothstein, we believe that our analysis has relevance beyond the NIH, and we disagree with his conclusion that the general approach to passive disclosure of results to family members we described *necessarily* violates the HIPAA privacy rule. In our article, we emphasized the importance of working with the executor of the decedent's estate. According to Mr. Rothstein, HIPAA *does* permit such disclosures if the executor seeks the information, which suggests that some minor adjustments to our approach might be appropriate for HIPAA-covered institutions. For example, in our conversation with Participant 1's partner, we could have suggested that she tell Participant 1's son (i.e., the executor of his estate) to contact us, instead of us initiating the call to him. Our article also emphasized the importance of facilitating communication among research participants and their relatives, which in turn will help ensure that relatives are aware of the existence of research results that they may wish to seek (via the executor) from researchers when the participant dies.

We hope that if "the vast majority of AJOB readers whose institutions are covered entities under the HIPAA Privacy Rule" (Rothstein 2012) determine that they should share results of deceased research participants with the participants' relatives, they will carefully evaluate how they can meet this obligation in a way that is HIPAA compliant, rather than dismissing the possibility altogether.

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