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Response to Open Peer Commentaries on "Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?"

Catherine Gliwa and
National Institutes of Health

Benjamin E. Berkman
National Institutes of Health and National Human Genome Research Institute

We greatly appreciate the open peer commentaries in response to our article about whether researchers should have an obligation to look for genetic incidental findings (Gliwa and Berkman 2013). Several of the commentaries helpfully expanded on our argument or demonstrated its application to specific cases (see, e.g., Costain and Bassett 2013; Price 2013; Ross and Reiff 2013). A few commentaries warrant further response.

Garrett (2013) argues that the obligation to return genetic incidental findings must be considered among broader social context and background conditions. We acknowledge and appreciate many of the questions Garrett raises about the wide-reaching implications of an obligation to look, especially questions about the role of the research enterprise and potential effects on future generations of researchers and participants. We agree with Garrett (and Anastasova, Blasimme et al. [2013], who voice a similar opinion) that the discussion of looking for genetic incidental findings should include the broader research and clinical care community, including physicians, genetic counselors, bioethicists, and so on. We suggest that the perspectives of these stakeholders can be included within our burden criterion. While in this article we focused on burden at a more granular level, we think that it is important and appropriate in future work to articulate how to expand the burden criterion effectively to include a broader consideration of impact on the research enterprise.

We agree with Anastasova, Blasimme and colleagues (2013) that robust informed consent is vital and that soliciting participants' preferences can greatly clarify which genetic findings should be sought or disclosed. In our article, we note that our framework is predicated on the assumption that participants have engaged in informed consent, and that an obligation to look for certain genetic findings is tied to an obligation to *offer* to disclose these findings, not an obligation to disclose them outright (Gliwa and Berkman 2013). Mobilizing filtering databases to operate based on participants' preferences may be a useful way to ensure

Address correspondence to Benjamin E. Berkman, Building 10/Room 1C118, 10 Center Drive, MSC 1156, Bethesda, MD, USA. berkmanbe@mail.nih.gov.

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informed consent plays an important role in prioritizing which variants should be looked for, if an obligation to look did arise.

Ulrich (2013) argues that the duty to rescue framework is better than the ancillary care framework at supporting the claims of our argument. We disagree. As one of his primary claims, he asserts that a rescue–based approach is preferable because it "recognizes the ethical duties researchers have toward the research study and offers a mechanism for appropriately balancing these with obligations to individual subjects" (50). Despite what Ulrich suggests, our framework does not overlook the ethical responsibilities the researcher has toward the institution of research and toward all participants. These responsibilities are included in our burden criterion, and are considered when determining the burden an obligation to look would place on the research team. He also argues that a rescue-based approach provides a "more definitive" (Ulrich 2013, 50) answer to the question of whether researchers should look for genetic incidental findings. We find this line of reasoning to be unconvincing; just because a principle provides a more definitive answer does not mean that it is necessarily a *better* answer. This is a highly complex subject, and our framework attempts to account for both the existing nuance and adjustments that will need to arise as genomic science and clinical care advance.

Finally, Biesecker (2013) criticizes the "impossibly high standards" we hold for evidence of benefit to participants (43). Biesecker's commentary, which states, "[T]hese authors reject *the policy of returning results* to genomics research participants" (43, emphasis added) and refers to "arguments for and against *returning results*," (43, emphasis added) suggests that he may have conflated the main question of our article (whether genetic incidental findings should be *sought*) with the broader issue of whether results should be returned. Specifically, our article questions whether there should be an obligation *to look* for genetic incidental findings incumbent upon all researchers performing whole-genome sequencing. As other commentators have noted, the burden of looking for incidental findings, however minimal, can accumulate when considered on a global scale. To justify this, the threshold for benefit to participants and uniqueness of access for participants must be especially high. While we agree that in some instances our language could have been more precise, we maintain that the quality threshold for implementing a wide-scale obligation to look for genetic incidental findings *should* be "well above that used in clinical practice" (Biesecker 2013, 43).

In response to Biesecker's claim that our article uses a "Nirvana (or perfect solution) fallacy to reject a policy" (43), we note that our article is not intended as a policy proposal but as a theoretical examination of when an obligation to look may exist. Compromises are inevitable when policy decisions must be enacted, but in this conceptual article we have the opportunity to imagine an ideal scenario. It is important to be exacting at this level so that when concessions are inevitably made, the boundaries of an actual policy are not inappropriately drawn.

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