



Published in final edited form as:

Genet Med. 2013 February ; 15(2): 157–159. doi:10.1038/gim.2012.162.

Return of Results in Genomic Biobank Research: Ethics Matters

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To the Editor

In “Return of Results from Genomic Biobanks: Cost Matters,” Bledsoe et al.¹ offer critique of a 26-author consensus article published in April’s *Genetics in Medicine* articulating the first full analysis of the challenge posed to biobanks by the debate over return of individual research results and incidental findings.² They raise important questions concerning the cost to biobanks. As lead author of the April paper, I write to respond.

Bledsoe et al. argue that our paper suggests responsibilities for biobanks that would impose “unsustainable” cost. Unfortunately, they do not address our own discussion of cost. Our paper suggested cutting back on what individual research results (IRRs) and incidental findings (IFs) should be returned in part because of cost: “The greater difficulty and cost of biobank return, the lower likelihood of benefit with lapse of time, and the reality that some contributors will not have consented to research, justify more restrictive criteria for return in biobank research than primary research.” And we included an important recommendation urging that “Research and biobank funders and regulators have a crucial role to play in making sure that research and biobank budgets adequately support responsible management of IFs and IRRs.” This recommendation can support biobanks as they articulate what resources they need to deal with return of IRRs and IFs.

The reality is that all research could be done less expensively and faster if we ignored ethical responsibilities to research participants. Ethics costs money and requires effort, starting with informed consent. The mere fact that dealing with return of IRRs and IFs will take effort and resources is not an argument against it. As yet, there are very few published studies analyzing the cost, especially in the complex context of a biobank research system. We defined that system to include (a) primary research or specimen and data collection sites, (b) the biobank itself, and (c) secondary researchers analyzing those specimens and data. As we pointed out, IRRs and IFs can arise at all three sites. Quantifying the cost of handling IRRs and IFs will not be easy. Cost will probably vary substantially depending on the design of the biobank research system and ethical choices made within that system on how to manage IRRs and IFs.

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Disclosures: Preparation of the April article to which Bledsoe et al. responded was supported by NIH/NHGRI grant 2-R01-HG003178 on “Managing Incidental Findings and Research Results in Genomic Biobanks & Archives” (S.M. Wolf, Principal Investigator; J.P. Kahn, F. Lawrenz, B. Van Ness, Co-Investigators). The author’s current work on return of results is supported by NIH/NCI/NHGRI grant 1-R01-CA154517 (G. Petersen, B. Koenig, S.M. Wolf, PIs) and Robert Wood Johnson Foundation (RWJF) Investigator Award 69763 (S.M. Wolf, PI). The contents of this letter are solely the responsibility of the author and do not necessarily represent the views of the full author group of the April article, NIH, NHGRI, NCI, or RWJF. The author of this letter has received honoraria for lecturing and participating in discussion on return of results, including from the Mayo Clinic and Boston Scientific.

Bledsoe et al. may overestimate the burden and costs we place on biobanks themselves. We carefully analyzed biobanks as one part of the larger biobank research system. This is because the purpose of biobanks is to aggregate data and specimens to fuel secondary research; biobanks enable the flow of data and specimens through the research system. Bledsoe et al. incorrectly suggest that we placed on biobanks alone the responsibility to establish criteria for evaluating IFs and IRRs, analyze those findings, reidentify participants, and recontact them to offer the findings. Instead, we urged that biobanks collaborate with primary researchers (or collection sites) and secondary researchers. Specifically, we recommended that biobanks work with both primary and secondary researchers to clarify criteria for evaluating findings, but should let primary researchers analyze findings arising at their own sites so that biobanks focus on those arising later in the biobank research system. We called for biobanks to collaborate with primary researchers to decide jointly how to handle reidentification, and we described different options including use of a “trusted intermediary.” However, once a participant is reidentified, we recommended that biobanks should generally leave the task of recontact to primary research sites when those sites have had direct contact with participants. Thus, our recommendations built in flexibility, so that different biobank research systems could allocate responsibilities within the system according to the research realities.

Bledsoe et al. appear to construe our paper as a “call for the routine evaluation and return of IFs and IRRs from all biobanks.” However, our paper discussed at length the variety of biobanks and noted that some biobanks cannot return IFs and IRRs because they irretrievably strip identifiers, making return of IFs and IRRs impossible. For those biobanks and biobank research systems retaining the capacity to reidentify and return, we urged the “development of explicit policy on whether IFs and IRRs will be returned.” We then recommended that the biobank research system differentiate the limited list of findings that “should” be returned from a potentially broader list that “may” be returned depending on decisions made within the biobank research system. Again, we built in considerable flexibility.

Bledsoe et al. conclude that the variety of biobanks argues against the kind of broad recommendations we offer and instead requires “case-by-case” analysis. However, the variety of biobanks does not make ethics recommendations futile. NCI’s Office of Biorepositories and Biospecimen Research has issued guidelines for biobanks,³ and a hefty literature offers ethics recommendations for biobanks, despite their variety. Many biobanks and biobank research systems are already trying to address return of results and looking for guidance. We offered analysis and concrete recommendations to advance the field.

Leaving biobanks and biobank research systems to face the return-of-results challenge one-by-one with no recommendations to guide them will reduce efficiency and increase costs, as biobanks struggle individually to figure out what to do. It will also do little to advance collective and coordinated consideration of what our research community owes individuals generous enough to provide their data and specimens. Presenting the kind of detailed analysis and concrete recommendations we offer in our paper is the necessary next step in the real world of genomic research powered by biobanks collecting data and samples. It sets the stage for future refinement of recommendations, as thinking progresses on how to advance research while advancing our collective understanding of ethical responsibilities.

Acknowledgments

Preparation of the April article to which Bledsoe et al. responded was supported by NIH/NHGRI grant 2-R01-HG003178 on “Managing Incidental Findings and Research Results in Genomic Biobanks & Archives” (S.M. Wolf, Principal Investigator; J.P. Kahn, F. Lawrenz, B. Van Ness, Co-Investigators). The author’s current work on return of results is supported by NIH/NCI/NHGRI grant 1-R01-CA154517 (G. Petersen, B. Koenig, S.M. Wolf,

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