▶ Support for Full Disclosure Up Front

"Models of Consent to Return of Incidental Findings in Genomic Research," by Paul Appelbaum et al. (July-August 2014), presents an interesting reconstruction of four models of consent to return incidental or secondary findings. We agree with the principles they use to evaluate the models: respect for persons, beneficence, and justice, principles set down in the *Belmont Report*. However, when drawing conclusions from their evaluation of these models, the authors focus too little on the importance of the ethical requirement of voluntary and autonomous choice and its precondition: full comprehension of the facts and circumstances prior to consenting (as Ruth Faden and Tom Beauchamp discuss in *A History and Theory of Informed Consent*). In genetic counseling and whole genome data collection, we always deal with the delicate topic of racism, discrimination, and eugenics, having seen in recent history the possible consequences of neglecting to respect individuals' autonomy. Genetic data, especially, demands an extensive information process prior to consenting, as it is linked to very personal, predictive, and determinative data.

As the authors explain, "respect for persons" "requires the provision of sufficient information for participants to make informed and meaningful choices." Similarly, as the *Belmont Report* indicates, this respect comprises the ethical conviction that "individuals should be treated as autonomous agents," and autonomy is therefore harmed when a person is denied information necessary to make informed and meaningful choices. Three of the four models Appelbaum et al. examine—the "staged consenting," "mandatory return," and "consent outsourcing" models—fail to sustain the standard of autonomous consenting and therefore do not adequately follow the principle of respect for persons.

The "traditional consent" model is the only model they examine that offers information on incidental findings prior to research participation. To counter the disadvantage, mentioned by the authors, that "participants' preferences may change after initial consent," traditional consent must be extended to an iterative consent process in time, with participants able to raise questions and express concerns that arise subsequently.

However, there still remains the disadvantage that the return of findings and the explanation process add to an already long and complex process, potentially hampering progress in medical research. Therefore, the consent discussion should be widened to a discussion about the availability of funding to create the infrastructure for a communication system regarding the disclosure of whole genome sequencing and whole exome sequencing findings to research participants, as the authors similarly explain. Attention should be given to research subjects' information requirements, as well as to the methods of transmitting information. In light of the Declaration of Helsinki, it can be argued that agents other than researchers and research sponsors, such as governments of host countries, must bear part of the costs of the obligation to communicate relevant health information. We propose simply that counseling be implemented as an interface between research and care support to comply with respect for persons.

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Appelbaum et al. refer to the criteria of "consistency with researchers' ethical obligations" and "practicality" when they state that selecting a model leads to inevitable trade-offs between normative implications. However, the question about the availability of resources to sustain autonomous consent does not change the ethical demand to pursue a consent model that can grant full information disclosure in the overall consent process.

In our opinion, in most models of the return of incidental or secondary findings, the criterion of practicality has overshadowed the ethical demand of respect for persons, which is achieved only through procedures that make possible the communication of adequate information. Information must enable participants to make informed and meaningful choices, even if protracted feedback processes are necessary. Thus, the question about the availability of resources to support and sustain autonomous consent cannot override the ethical evaluation of consent models. The availability of and funding for these resources can be considered a topic in itself to improve health services and research infrastructure so that they are compatible with the highest attainable realization of ethical principles.

• ***Felicitas Holzer***
University of Buenos Aires
• ***Ignacio Mastroleo***
Consejo Nacional de Investigaciones Científicas y Técnicas

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