Dear Miss Holzer:

Thank you for your submission "Models of consent to return incidental findings that skip full information disclosure before research enrollment cannot be ethical." We would like to publish your response to the article by Paul Appelbaum et al. in the Exchange section of the Hastings Center Report. We would, of course, edit the piece for style, accessibility, and length.

As we understand it, the commentary’s main point is that the debate about the return of incidental findings does not adequately address the importance of funding the development and sustainment of a communication infrastructure that will allow for true respect for persons at all possible stages with respect to the return of such findings. In shortening the piece for Exchange, our aim will be to make your most important points more prominent. Therefore, we will retain these points: your argument that Appelbaum et al. underplay the importance of participants’ full comprehension of facts and circumstances prior to consenting; your assertion that this comprehension—and this timing of it—are, however, essential for respecting persons and their autonomy; your proposal that counseling be provided to participants so that they can receive the information they need at each and every stage to make informed decisions; and the assertion that the field needs to take up more thoughtfully and directly the topic of funding this sort of communication infrastructure. We will omit lines, such as the bullet points, that are not essential to your main points. We will also need to use a considerably shorter title.

Please let me know if this plan for editing down your submission does not convey your intentions in the commentary.

We will provide Appelbaum et al. the opportunity to write a reply to your piece.

Thank you again for contributing a response to the article. We look forward to seeing it into publication.

Sincerely,

Laura Haupt
Managing Editor, Hastings Center Report
hauptl@thehastingscenter.org

[Email ref: DL-SW-ACC-wor]

Date Sent: 25-Nov-2014
Model of consent to return incidental findings that skip full information disclosure before research enrollment cannot be ethical

Authors

Felicitas Holzer, felicitasholzer@gmx.de; Master Student, International Master Program in Biomedical Sciences, Universidad de Buenos Aires, University of Freiburg; Ignacio Mastroleo, ignaciomastro@gmail.com; Program of Bioethics FLACSO Argentina-CONICET, UBA, PAHO Foundation

Abstract


The paper written by Appelbaum et al. presents an interesting reconstruction of four models of consent to return incidental or secondary findings which they call: “staged consenting”, “mandatory return”, “consent outsourcing” and “traditional consent”. Furthermore, they assess the four models with the criteria of “consistency with researchers’ ethical obligations” and “practicality” (Appelbaum et al 2014:29).

We agree with the guiding principles to evaluate the models, given by the criterion “consistency with researchers’ ethical obligations”, namely, “respect for persons, beneficence, and justice” which refer to the basic principles of research ethics settled in the Belmont Report (National Commission 1979).

However, when drawing the conclusion of their evaluation, 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 (Faden and Beauchamp 1986). In the new field of genetic counseling and whole genome data collection, we always deal with the delicate topic of racism, discrimination, and eugenics that showed us in recent history the possible consequences of missing autonomy. Especially genetic data demands an extensive information process prior to consenting as it is linked to very personal, predictive and determinative data.

As the authors explain, the criterion of “respect for persons”, “…requires the provision of sufficient information for participants to make informed and meaningful choices” (Appelbaum 2014:29). Similarly, “respect for persons” comprises the ethical conviction that “…individuals should be treated as autonomous agents” (National Commission 1979). Therefore, autonomy is
The “traditional consent” model is the only model suggested by Appelbaum et al. (2014) 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” (Appelbaum et al. 2014:24), the “traditional consent” must be extended to an iterative consent process in time, in which participants are able to utter questions and concerns that arise subsequently.

However, there still remains the disadvantage that the feedback of findings and the explanation process adds to an already long and complex process which potentially hampers 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 WGS (whole genome sequencing)/WES (whole exome sequencing) findings to research participants, as the authors similarly explain. Attention should be given to information requirements of research subjects, as well as to the methods to transmit information. Considering the pillars of the WMA Declaration of Helsinki (WMA 2013), it can be argued that other agents than researchers and research sponsors, such as governments of
host countries, are required to bear part of the costs of communicative obligations of relevant health information. Our proposal just states that counseling could be implemented as an interface between research and care support to comply with respect for persons.

Appelbaum et al. (2014:30) state that selecting a model leads to inevitable tradeoffs between normative implications, referring to the two criteria “consistency with researchers’ ethical obligations” and “practicality”. However, the question on the availability of resources to sustain autonomous consent does not change the ethical demand to pursue a consent model that is able to grant full information disclosure in the overall consent process. In our opinion, the criterion of practicality overshadows the ethical demand of respect for persons which is only reached by adequate information procedures. Information must grant informed and meaningful choices by the participants, although protracted feedback processes might be necessary. Thus, the question on the availability of resources to support and sustain autonomous consent cannot override the ethical evaluation of consent models. It can be considered a topic in itself to improve health services and research infrastructure to make them compatible with the highest attainable realization of ethical principles.

References


