Decision Letter (HAST.20140028)

From: hauptl@thehastingscenter.org

To: felicitasholzer@gmx.de

CC: kaebnickg@thehastingscenter.org, ignaciomastro@gmail.com

Subject: the Hastings Center Report - Decision on Manuscript ID HAST.20140028

Body: 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

Manuscript submitted to The Hastings Center Report 13-Oct-2014

Title

Models of consent to return incidental findings that skip full information disclosure before research enrollment cannot be ethical

Authors

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Abstract

A commentary on “Models of Consent to Return of Incidental Findings in Genomic Research” by Paul S. Appelbaum, Erik Parens, Cameron R. Waldman, Robert Klitzman, Abby Fyer, Josue Martinez, W. Nicholson Price II, and Wendy K. Chung, in the July-August 2014 issue.

The paper written by Appelbaum etal. 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

harmed when withdrawing a person from information necessary to make informed and meaningful choices (National Commission 1979).

Following the principle of “respect for persons”, the models of “staged consenting”, “mandatory return” and “consent outsourcing” fail to sustain the standard of autonomous consenting (Appelbaum et al. 2014, Table 1):

- In the “staged consenting” model, participants receive information about incidental findings later, as they arise. This skips the information process prior to research participation. Hence, at the point of time of decision making whether to participate or not, full comprehension and thus, an autonomous consent cannot be achieved.
- The “mandatory return” model leaves the obligation to feedback incidental findings completely in the researcher’s hands. Participants agree initially to receive specified incidental findings, transferring the task of decision making to the researcher. Therefore, this model of return on incidental findings does not respect the individual freedom of the participant to act on personal judgments that can potentially change after the initial agreement.
- In the “consent outsourcing” model, the raw genetic data material is given to participants who then can make use of second services analyzing that data. At the point in time of data collection, the participant has not yet been counseled on possible benefits and risks. Thus, it might be possible that participants decide not to access their information after research participation, although researchers already discovered important findings which are eventually not communicated. Hence, full comprehension prior to enrollment is not achieved.

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 thatcounseling 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

Appelbaum, P., Parens, E., Waldman, C., Klitzman, R., Fyer, A., Martinez, J., Price, N., Chung, W. (2014). “Models of Consent to return of incidental findings in genomic research”. Hastings Center Report 44, 4.

Faden, R., Beauchamp, T. (1986). “A history and theory of informed consent”. New York/Oxford: Oxford University Press.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). “The Belmont Report”, Washington DC: U.S. Government Printing Office,http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

World Medica Association (WMA) (2013). “Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.”, http://www.wma.net/en/30publications/10policies/b3/