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Alternative consent approaches for biobank research

What constitutes ethical research in human beings has always been contested, and much debate has thus ensued over the meaning and practice of informed consent. Is informed consent always necessary from individuals who participate in research? What does it mean to be informed about a research study? Can other people give proxy consent for individuals who cannot do so—eg, adults who are incapacitated such that they cannot make the decision or children? Do the answers to these questions depend on the type of research to be done, or are they the same for all categories of research?

In this month's *The Lancet Oncology*, Hansson and colleagues,¹ contend that individuals do not need to give specific consent for future use of their biological samples for biobank research to be ethical. They do, however, reject the idea of blanket consent, in which individuals would consent to any type of future research with their samples. Instead, they propose a middle-ground of broad and future consent, which avoids researchers having complete freedom to do whatever they want with biobank samples, yet increases the number of samples likely to be available for future research compared with an approach that requires researchers to recontact individuals to obtain consent for every new study. The model of broad and future consent is contingent on ensuring that personal research-related information is handled safely, that donors can withdraw consent at any time, and that an ethics review board approves new studies or changes to the legal or ethical authority of a biobank.

The investigators argue that when the risks of research are low and sufficiently well controlled, autonomy is expanded rather than restricted when individuals are given the opportunity to decide whether they want to accept this level of risk for future use of their samples.

Yet, they define risks narrowly, focusing only on improper access to and misuse of personal research-related information. In addition, consequential harms could be incurred—research with biobank samples could lead to discrimination by employers or health-insurance companies and to stigmatisation against individuals and social groups who are genetically at risk of developing a specific disease. Individuals and groups might also be exposed to dignitary harms from research—eg, if their biological samples are used in a way that violates their religious, personal, or community values.^{2–4}

At least three concerns have emerged from calls to relax the traditional model of specific consent (calls that extend beyond those of the biobank context). First, the definition of risk has yet to be adequately defined. Is risk only about access to and use of personal information? What about consequential and dignitary harms? What constitutes less risk, and what constitutes more risk? Second, ethics review boards could have widely differing definitions of risk; research approved by the ethics review board of one biobank might not pass review at a different biobank. Third, the public generally does not have access to information about decisions made by ethics review boards. Although projects such as the UK Biobank and the Quebec CARTaGENE biobank are being developed through a process of public consultation,⁵ whether the public will have full access to information about the decisions made by ethics review boards for these and other projects is unclear. In the USA, ethics review boards are not required to provide the public with information about the number of research proposals they review, the nature of the research proposed, or the outcome of their review, including any ethical issues that might have been disputed. Without this

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information, how will individuals who give broad and future consent know that ethics review boards only approved research that met the conditions of this consent approach? Will an independent organisation be in place to ensure that the conditions are met? For example, national legislation in Estonia for the Estonian Genome Project requires that a governing board be established to monitor the biobank's activities; an independent national ethics committee provides general ethical oversight of the biobank.⁵ In the UK, the Ethics and Governance Council, which is independent structurally and financially from the UK Biobank, has been established to ensure that the biobank's activities, protocol, and procedures comply with the project's Ethics Governance Framework.⁵ Both these projects require individuals to give blanket consent for future use of their biobank samples.

The legitimacy of alternative-consent approaches hinges on the adequacy of governance mechanisms to protect confidentiality of personal information, facilitate withdrawal of consent, and ensure that ethics review boards fulfil their obligation to approve only studies that meet the conditions of these models. Accountability, transparency, and proper monitoring are crucial to maintain public trust in biobank research,⁵ especially if individuals give consent for future research with their biobank samples before an ethics review board has approved specific studies. Whether oversight mechanisms such as those for the Estonian

Genome Project and the UK Biobank will ensure that alternative consent approaches do not undermine public trust in biobank research or render the principle of informed consent meaningless remains to be seen.

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I declare no conflicts of interest.

- 1 Hansson MG, Dillner J, Bartram CR, et al. Should donors be allowed to give broad consent to future biobank research? *Lancet Oncol* 2006; **7**: 266–69.
- 2 Rothstein MA, Expanding the ethical analysis of biobanks. *J Law Med Ethics* 2005; **33**: 89–101.
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Errata

Mathew P, Vakar-Lopez F, Tronsco P. Protracted remission of metastatic epithelioid angiosarcoma with weekly infusion of doxorubicin, paclitaxel, and cisplatin. *Lancet Oncol* 2006; **7**: 92–93—The third paragraph should have read: the patient began hormone-ablative treatment with a monthly injection of 7.5 mg leuporelin intramuscularly for 3 months.

Al-Terkait F, Charalambous H. Severe coagulopathy secondary to vitamin K deficiency in patient with small-bowel resection and rectal cancer. *Lancet Oncol* 2006; **7**: 188—The third line should have read: resection of low anterior rectal cancer.



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