

ANALYSIS

Biobank research: who benefits from individual consent?

Requiring informed consent for research on stored tissue samples and associated data safeguards the autonomy rights of donors. But **Joanna Stjernschantz Forsberg**, **Mats Hansson**, and **Stefan Eriksson** argue that this policy not only defeats the interest of society but also runs counter to the interests of the individuals it purports to protect

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Much of the research on which our healthcare knowledge is based has not been carried out under circumstances that would be considered morally acceptable today. Scandals such as the experiments of the Nazi doctors,¹ the Tuskegee syphilis study,² and the retention of organs from children in Alder Hey³ have evoked much anger and contempt. In an attempt to protect people from such offences extensive regulations have been put in place.

In many countries, including the United Kingdom and Sweden, requiring informed consent has become the default position not only for invasive research but also for non-interventional research, such as using leftover material taken within the healthcare system.⁴ Other countries (including Denmark and Belgium) permit presumed consent for such research. In this article we argue that well intended regulations governing biobank research (defined as research on stored tissue samples and associated data) cause harm by hampering medical advances.

Argument for informed consent

Individuals are often claimed to have a right to control how their personal data and samples are used, even if no risks are involved.⁵⁻⁶ From this rights based perspective Alberta law professor Timothy Caulfield has argued that: "While the protection of confidential information is clearly important, respecting autonomy requires much more than simply ensuring that confidentiality is maintained. In the realm of biobanks, autonomy is largely about the maintenance of control over something that implicates personal integrity."⁷ Stanford law professor Henry Greely has similarly claimed that individuals have a dignitary interest in controlling their medical records and tissues⁸ and that a person has an interest in consenting or not consenting to be part of research even if participation is limited to the use of previously collected data or samples.⁹

The Unesco International Declaration on Human Genetic Data states that prior, informed consent should be obtained for the

collection, storage, and use of biological samples, and limitations on the principle of consent by domestic law "should only be prescribed for compelling reasons."¹⁰ The Council for International Organizations of Medical Sciences' guidelines on epidemiological studies also call for individual informed consent, stating that waiver "is to be regarded as exceptional."¹¹ Thus, instead of being an instrument used to protect individuals against coercion and deception,¹² informed consent has, in the context of biobank research, seemingly become a right to agree or disagree to research itself.

Cost of informed consent

Requiring informed consent for biobank research causes problems for at least two reasons. Firstly, obtaining consent for research on stored samples and data consumes resources that could be used for more research or healthcare. An obvious example is when researchers wish to use leftover material that has been taken during healthcare and there is no consent for research. Time and money must then be spent on tracing the sources of the samples, perhaps many years after the material was excised.¹³⁻¹⁴ Furness and Nicholson attempted to obtain informed consent for research on surplus material from 495 renal transplant patients. After one year the opinion of 26% of the patients had still not been ascertained.¹⁵ The authors concluded that demands for explicit consent may have led to the abandonment of many research projects in the UK.¹⁵ Similarly, in New Zealand a planned study on the prevalence of gene mutations for long QT syndrome was not done because informed consent was deemed "too logistically difficult" to obtain.¹⁶ Obtaining specific consent also causes problems if researchers subsequently want to use the samples for a different study.

Secondly, well documented differences between individuals who consent to participating in biobank research and those who

do not¹⁷⁻²⁰ can threaten the validity of the results.²¹ If we, not unrealistically, assume that 70% of those contacted respond, and 5-10% of those who reply refuse consent, the missing data can obviously result in biased results.

Both of these problems can be reduced if broad, presumed, or no consent for research on leftover material is accepted. Under the first policy, people are asked to consent to a wide range of research so that they do not need to be contacted every time a new project is initiated. Under the second, consent is presumed unless they opt out. The third option is to allow research without obtaining (new) consent after approval by an ethics review board. But even the least controversial of these proposals, that of broad consent, has been extensively criticised, partly because it breaches autonomy,^{6-9 22} although as we have argued previously, a wider view of autonomy would allow for it.²³

Individual rights versus the public good?

The conflict between the need to obtain consent and the consequences of doing so is often viewed as a clash between individual rights and the public good. On the one hand individuals have a right to decide whether a sample can be used for research; on the other requiring informed consent hampers research and hinders medical progress, which runs counter to the interest of society.

Of course, individuals have interests not only as research subjects but also as patients and citizens. And given that nobody knows how much and what kind of medical care they and their family and friends will need in the future it can be argued that everybody has a vested interest in new research. So rather than weighing the rights of the individual against the public good, the interest of the individual as a research subject should be balanced against the interest of the same individual as a direct or indirect beneficiary of healthcare. Since the risks imposed by biobank research are minimal (with appropriate safeguards such as adequate data protection and ethical approval) the interest of the individual as a research subject is outweighed by his or her interest in medical advances. Furthermore, because robust research depends on access to samples and data from as many people as possible, a system that facilitates general contribution is in the interest of all.

Shared goals and mutual benefits

As individuals living together in a society we limit our freedom in many ways to achieve common goals. We pay taxes, although we know that the money may be used for purposes that we do not support. We acknowledge regulations ranging from traffic rules to compulsory education and military service. We accept public health interventions such as smoking bans and mandatory contact tracing for certain diseases. When the stakes are sufficiently high and the cost seems acceptable, instead of relying on voluntary action (or inaction) we impose regulations. These regulations are often based on public benefit, but sometimes they can be defended from the perspective of pure self interest as well. Shared goals that are unattainable by us as individuals can be reached through collective efforts; to gain the mutual benefits we must accept some restrictions of our personal freedom.

This argument is applicable to biobank research. It is therefore rational to accept that samples are used for research without obtaining informed consent.

It is often argued that not requiring individual consent cannot be justified because the research will not benefit the person from whom the sample was taken, since it is unlikely that the

knowledge obtained will be relevant to him or her. However, it is not clear why the benefit must be generated by research on material from the specific individual; it could as well be the result of research on any other sample—that is, a result of the existence of the research enterprise or the biobank, as such. Just as I benefit from a clean environment regardless of who has refrained from polluting it, I benefit from increased medical knowledge obtained through biobank research regardless of whose sample has been used.

It is reasonable to view biobank research in this way because the risks are minimal. The same line of reasoning also applies to other non-interventional research, such as using medical records or registries. It can't, however, be used to justify participation in invasive research because in this case it is not clear that the benefit outweighs the risks for the individual (even though it is likely that the public benefit would).

Conclusion

Accepting this proposed view on biobank research implies that this research is considered to be a natural component of healthcare that is endorsed and facilitated, just like quality control, method development, and teaching. Leftover material, stored tissue samples, and associated data can be used without consent, after approval by an ethics review board, because the minimal risk of harm is clearly outweighed for each individual by the increased chance of benefiting, directly or indirectly, from healthcare.

Contributors and sources: JSF has studied ethical aspects of biobank research, in particular concerning consent and returning results. MH and SE have long research interests in biobank ethics and have published widely in the field. JSF wrote the first draft of the article. All authors contributed to the analysis and critical revision for important intellectual content and have approved the submission of the final version of the article. JSF is the guarantor.

Funding: The research for this article was supported by the EU sixth framework programme AutoCure and by the Swedish Research Council through BBMRI.se. The funders had no role in the research process and the article reflects only the authors' views. The funders are not liable for any use that may be made of the information herein.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Accepted: 14 August 2011

Cite this as: *BMJ* 2011;343:d5647

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