

## **Empirical research on informed consent and biobanks**

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### **Introduction**

Obtaining the informed consent of patients and research subjects is now an expected part of clinical medicine and research. Offering the individual the right to refuse participation, or revoke an informed consent without risking any negative consequences on subsequent care, protects the autonomy of the individual<sup>1</sup>.

The rapid development of biotechnological research has stimulated the establishment of new biobanks, and the use of existing biobanks. The Swedish National Board of Health and Welfare suggests that informed consent must be present when collecting information for new biobanks<sup>2</sup>. However, the situation is more complicated in relation to already existing biobanks, since it is often uncertain whether previous consent exists or not. The Swedish Research Council recommended in their guidelines that the use of existing biobanks should be accompanied by approval by the research ethics committee, which may lead to practical and methodological problems<sup>3</sup>. It is of immense concern to balance the possible conflicts of interests that may come up, i.e., sample donors' and their relatives' integrity/autonomy versus altruism. Up until now, no empirical studies have explored these issues in the context of biobanks. Knowledge of potential sample donors' perceptions regarding the use of biobanks is valuable in developing appropriate informed consent procedures for use in clinical practice and in research settings.

The overall aim is to empirically identify perceptions of the general public, blood donors and patients regarding i) risks and benefits of the use of biobanks, and ii) informed consent procedures in relation to the use of material from biobanks.

### **Material and methods**

The study is based on a self-administered questionnaire that will be sent to a random sample of i) the general public; ii) blood donors; and iii) patients. In the questionnaire, the respondents are asked to rate the risks and benefits that they believe are associated with different uses of biobanks. A number of realistic examples will be presented for this purpose. The examples cover use of material from biobanks in a variety of research settings and in clinical practice, e.g. screening for phenylketonuria, development of pharmacogenetic tests, and routine diagnostic procedures. For each example, the respondents will be asked to grade perceived risks and benefits to themselves, their relatives and, actual and future patients on a Visual Analogue Scale. Next, the respondents are asked to state whether they would consent or refuse to participate in the examples given. In a second part of the questionnaire, the respondents will also be asked to tie a preferred consent procedure to each example. The options include i) no consent required, ii) informal consent procedure with access to

information up on request, and iii) extensive written informed consent procedure. The questionnaire will also include demographic variables and, for example, risk attitudes/behaviour and sense of coherence.

## Results and implications

This design will make it possible to identify efficiency-pleaders and integrity-pleaders. Efficiency-pleaders would be those who choose informal consent procedures, even though the risks are considerable and the benefits are limited. Integrity-pleaders, on the other hand, are those who require extensive written consent procedures even though the benefits are substantial and the risks limited. There may be several intermediate “pleaders” between these two extremes. The results will form the basis for recommendations of how informed consent may be obtained in relation to the collection/use of material in biobanks.

## References:

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<sup>1</sup> Faden, R. R & Beauchamp, T. L., *A history and theory of informed consent*. Oxford: Oxford University Press; 1986.

<sup>2</sup> National Board of Health and Welfare: Biobanks in health care etc (Biobanker i hälso-och sjukvården mm). 2000.

<sup>3</sup> The Swedish Research Council: Research ethical guidelines for biobanks (Forskningsetiska riktlinjer för biobanker). 1999