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*Centre for Research Ethics & Bioethics*

# **Biobank Ethics Report**

## **May 2009**

## Biobank ethics

For many years, researchers at CRB have provided constructive advice on how to deal with ethical aspects of research using human tissue material. We have collaborated with biomedical scientists and published our findings in peer reviewed journals. As a summary of this research we have compiled a list of publications with abstracts. This report was updated in May 2009.

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**Stjernschantz Forsberg J, Hansson MG, Eriksson S. "Changing perspectives in biobank research – from individual rights to concerns about public health regarding the return of results". *European Journal of Human Genetics*, advance online publication, May 27 2009.**

**Abstract:** During the last decade, various guidelines that imply a duty for researchers to disclose information obtained through research to participants have emerged. The character and extent of this obligation have been debated extensively, with much attention devoted to the decisiveness of the validity and utility of the results in question. The aim of this paper is to argue that individual results from research on materials stored in large-scale biobanks, consisting of samples taken within the healthcare system or of altruistically donated material, should not be returned. We will defend the thesis that medical research on these biobanks should be viewed as a collective project to improve public health, and that available resources should be utilized to pursue this goal. We argue that there is a need for a change of perspectives. Medical research should not primarily be viewed as a danger that individuals must be protected from, but rather be recognized as constituting a necessary defense against current and future disease. Research that bears the prospect of advancing medicine and that can be carried out at no risk to individuals should be endorsed and facilitated. This calls for a shift of focus from autonomy and individual rights toward collective responsibility and solidarity.

[Abstract and link to full text >](#)

**Hultman, CM, Lindgren, A-C, Hansson, MG, Carlstedt-Duke, J, Ritzen, M, Persson, I, Kieler, H, Ethical Issues in Cancer Register Follow-up of Hormone Treatment in Adolescence, *Public Health Ethics* 2009;2(1):30-36**

**Abstract:** Since the 1970s, estrogen have sometimes been used in adolescent girls to reduce very tall adult expected height. Worries about long-term effects have led to a proposal to link treatment data with cancer registers. How should one deal with informed consent for such a study? We designed a qualitative study with semi-structured telephone interviews. From 1200 women who were to be followed-up in cancer registers, we randomly selected 22 women. Major themes were a wish to be involved and a positive attitude to the proposed register research. The women did not express worry after reading the study protocol, but did convey considerable frustration that this research had not been initiated earlier. Active consent was not seen as crucial. We found strong interest in a high participation rate and a concern over missing data. The selection of information and consent or the decision to go ahead without consent in register follow-up is a delicate balancing act. Study participants wish to be contacted, but acknowledge the primary goal of answering important questions. Our study provides support for safeguarding privacy in epidemiological linkage studies and in follow-up of medical treatment without losing the scientific value by requesting for informed consent.

[Abstract with link to full text >](#)

**Hansson, MG, Ethics and Biobanks, British Journal of Cancer 2009;100, 8–12**

**Abstract:** Biobank research has been the focus of great interest of scholars and regulatory bodies who have addressed different ethical issues. On the basis of a review of the literature it may be concluded that, regarding some major themes in this discussion, a consensus seems to emerge on the international scene after the regular exchange of arguments in scientific journals. Broad or general consent is emerging as the generally preferred solution for biobank studies and straightforward instructions for coding will optimise privacy while facilitating research that may result in new methods for the prevention of disease and for medical treatment. The difficult question regarding the return of information to research subjects is the focus of the current research, but a helpful analysis of some of the issues at stake and concrete recommendations have recently been suggested.

[Abstract with link to full text >](#)

**Johnsson L, Hansson MG, Eriksson S, Helgesson G, Opt-out from biobanks better respects patients' autonomy, BMJ 2008;337:a1580**

Debate. [Link to full text >](#)

**Johnsson L, Hansson MG, Eriksson S, Helgesson G, Patients' refusal to consent to storage and use of samples in Swedish biobanks: cross sectional study, BMJ (Clinical research ed. 2008;337:a345**

**Abstract:** OBJECTIVES: To estimate how many people object to storage of biological samples collected in health care in Sweden and to their use in research and how many withdraw previous consent. DESIGN: Cross sectional study of register data. SETTING: Biobanks used in Swedish health care, 2005-6. POPULATION: Data on refusal to consent were obtained for 1.4 million biobank samples per year from 20 of 21 counties. MAIN OUTCOME MEASURES: Rates of preliminary refusal to consent, confirmed refusal, and withdrawal of consent. RESULTS: Patients refused consent to either storage or use of their samples in about 1 in 690 cases; about 1 in 1600 confirmed their decision by completing a dissent form. Rather than having the samples destroyed, about 1 in 6200 patients wanted to restrict their use. Of those who had previously consented, about 1 in 19 000 withdrew their consent. CONCLUSIONS: Refusal to consent to biobank research in Sweden is rare, and the interests of individuals and research interests need not be at odds. The Swedish healthcare organisation is currently obliged to obtain either consent or refusal to each potential use of each sample taken, and lack of consent to research is used as the default position. A system of presumed consent with straightforward opt out would correspond with people's attitudes, as expressed in their actions, towards biobank research.

[Abstract with link to full text >](#)

**Hansson, Mats G., *The Private Sphere. An Emotional Territory and Its Agent*, Springer, Series: Philosophical Studies in Contemporary Culture, 2008;15(x), ISBN: 978-1-4020-6651-1**

**Abstract:** The non-interference perspective is common when theorizing about the protection of the private life of individuals and their families. However, this accepted way of looking at things, leads our thoughts astray. It fails to do justice to the interests both in being left in peace but at the same time participating in a community together with other people. New methods of communications interception, video and even satellite surveillance allow insight and an entry into personal matters, but they can also be used to satisfy people's need for protection, safety and security in public places. Genetic research and research using human tissue material has provided insight into the individual's genetic material in a way which was previously impossible, thereby allowing new possibilities for the diagnosis and treatment of hereditary illnesses. Individuals have an interest in non-interference but also an interest in profiting from the results, which such interference can give. A theory about the respect for the individual's right to a private sphere and its protection ought therefore to incorporate both these interests.

In *The Private Sphere* it is suggested that an emotional territory, which forms the individual's own sphere of action and experience, has developed in the course of evolution in pace with the individual's conditions of life, brought about by challenges in the natural and social environment. The starting point is the insight that the behaviour of human beings with respect to their privacy reflects in a fundamental way patterns of behaviour among social animals. The emotional territory allows a readiness to act along different lines and to maintain a multiplicity of different social relations. As described in a concluding chapter, this way of looking at privacy interest will have important consequences for the regulation of biobank research.

[More information and orders >](#)

**Hansson, M.G., *The need to down regulate. A minimal ethical framework for biobank research*, in: Dillner, J. (ed), *Methods in Bio-banking, Methods in Molecular Biology Book Series*, The Humana press, Inc Totowa, NJ USA 2007 (In press).**

**Abstract:** There are currently multiple international bodies suggesting legal and ethical frameworks for regulating international biobank research. One will for obvious reasons find inconsistencies in terminology and differences in procedures suggested for biobank research among all those guidelines, emanating from many different moral and legal traditions. A central question is if this constitutes a threat to making progress in international biobank research, as some have argued. In this bookchapter I suggest that there are sufficient and well-established instruments and ethical principles available to guide research in this area. Basically I argue that there is no need for a top-down superstructure of detailed rules and guidelines to be imposed on biobank researchers. With the existing ethical review boards playing a central role guided by well-established ethical guidelines (e.g. the Helsinki Declaration) self-regulation by researchers providing arguments for balancing of interests in association with different research initiatives and protocols will be sufficient. Traditional information and consent procedures suffice and data protection implies a sovereign right of the individual citizen to grant the use of biobank material and personal data that is needed for biobank research. Clearly, there may still be inconsistencies in terminology when researchers

of different nationalities meet in common enterprises, but both they and the ethical review boards are well equipped to sort out what is actually meant and propose different instruments for, e.g. coding. The existing ethical review boards should play the key role, guided by the sound argumentation by the researchers in their application to the board.

**Helgesson, G., Dillner, J., Carlson, J., Bartram, C.R., Hansson M.G., Ethical framework for previously collected biobank samples, *Nature Biotechnology*, 2007;25:973-976.**

**Abstract:** Biobanks, i.e. systematic collections of biological samples, are important resources for health. The pooling of such resources in international scientific studies amplifies their potential scientific value. However, national and international legislation, ethical guidelines, and a multiplicity of patient/donor interests must be addressed as well as scientific considerations if such research is to be successful. This article addresses the selection of appropriate information and consent procedures when previously collected samples are used in international cooperation. Although informed consent is a standard ethical requirement for medical research, the circumstances for research on existing biobanks are sufficiently different to motivate a specific praxis. An ethical framework for research on previously collected biobank samples is presented. Based on this, recommendations adapting to existing forms of consent are provided.

[Abstract and link to full text >](#)

**Hansson, M.G., For the safety and benefit of current and future patients, *Pathobiology*, 2007;74:198–205.**

**Abstract:** Pathology biobanks are vital assets for medical care and treatment of current and future patients. In association with good clinical data they are also useful for biomedical research regarding the underlying mechanisms of human disease. Recent regulations have suggested the obtainment of a specific and explicit informed consent as a prerequisite for using human tissue samples with these ends in mind. However, the choice and strict use of informed consent for balancing conflicting interests associated with biobank related research can in practice be detrimental to patient safety with regard to diagnosis, medical care and treatment. In this article I argue that a “safety principle” should have priority and suggest how this could be implemented in clinical practice and in association with biomedical research.

[Abstract and link to full text >](#)

**Hansson, M.G., Helgesson, G., Wessman, R., Jaenisch, R., Isolated stem cells – patentable as cultural artifacts?, *Stem Cells*, 2007;25:1507-1510.**

**Abstract:** This article argues that an isolated embryonic stem cell (ES) basically represents a culture artifact that has no equivalent to cells of the embryo and that it is likely that the isolation of adult stem cells has a similar consequence. An isolated stem cell could thus be distinguished as something else than the stem cell existing as part of a human body. Since isolation of stem cells implies modification, product patents should, where the results carry enough novelty, inventive step and potential for industrial application, as a matter of principle

be a viable option for patent authorities. Questions of morality, which may affect the patentability, should also be viewed in the light of the distinction between isolated result and body part. At the same time it is essential that patent authorities do not accept broad patent claims that will be detrimental to research.

[Abstract and link to full text >](#)

**Helgesson, G., Eriksson, S., Swartling, U., Limited Relevance of the Right Not to Know—Reflections on a Screening Study, Accountability in Research: Policies and Quality Assurance, 2007;14(3):197-209.**

**Abstract:** The right not to know personal health-related information has been included in prominent human rights documents and subsequently in national legislation since the middle of the 1990s. Apart from situations where another life is at stake, the right not to know has in these documents been formulated as if it should have precedence over other interests. This article argues against giving the right not to know such a prominent position. It does so by questioning the ethical relevance of the concept for both theoretical and empirical reasons. The main focus of the article is on empirical data from a prospective population screening for Type 1 diabetes. Data indicate that research participants are not as autonomous as is generally assumed by the defenders of the right not to know.

[Abstract and link to full text >](#)

**Swartling U, Eriksson S, Ludvigsson, J, Helgesson G., Concern, pressure and lack of knowledge affect choice of not wanting to know high-risk status, European Journal of Human Genetics 2007;15:556–562.**

**Abstract:** The 'right not to know' one's genetic status has been increasingly more recognised in ethical and legal instruments. Yet empirical research is limited, leaving discussion on a theoretical level. There are also divergent ideas as to what extent it should be respected. In this study, we explored the clinical preconditions for disclosure of increased risk of getting diabetes in children. We included questions in the clinical 5-year questionnaire of a predictive screening for the risk of type 1 diabetes (T1DM), asking the respondents (n=7206) whether they wished to be informed of their children's potential risk status. The group of 2% of the respondents who did not want to know about risk status proved to be significantly associated to concern with natural history data (OR 4.03), lack of knowledge (OR 3.17), pressure to participate (OR 2.99) and the child's disease development (OR 2.18). We discuss whether parents'/participants' 'no' to high-risk information may call for a more nuanced response such as information and support, rather than simply respect their wish not to know. We furthermore argue that it is ethically questionable whether the parents' expressed wish not to know should prima facie override the potential benefits for their child. We conclude that this constitutes sufficient reason not to promote a default solution where people's expressed wishes not to know are taken at face value.

[Abstract and link to full text >](#)

**Kettis-Lindblad Å, Ring L, Viberth E, Hansson, M.G., Perceptions of potential donors in the Swedish public towards information and consent procedures in relation to use of human tissue samples in biobanks: A population-based study. Scandinavian Journal of Public Health 2007;35(2):148-156.**

**Abstract:** Aims: To assess the Swedish public's preferences for information and consent procedures when being asked for permission to use previously collected tissue samples for new research studies. Methods: Cross-sectional study employing postal questionnaires to a random sample of the Swedish general public (n56,000) in October 2002–February 2003. The response rate was 49% (n52,928). This paper includes only respondents who reportedly would approve of samples being taken and stored (n52,122). Results: When potential tissue sample donors in the general public have to strike a balance between the values at stake, i.e. the autonomy of the donor versus the research value, most (72%) prefer general consent, i.e. where consent is asked for at the outset only. They want the research ethics committee (REC) alone to decide on the use of stored samples, and they would allow storage as long as the sample is useful for research. The minority of respondents who were in favour of specific consent were more likely to be young, well educated, have negative experiences of healthcare and low trust in healthcare authorities. Conclusions: The majority of the Swedish general public prefer general consent, and are thus willing to delegate some decisions to the RECs. However, preferences for information and consent procedures depend on the context, e.g. the risks for the donor and the purpose of the research. If feasible, procedures should be differentiated according to the preferences of individual donors, thus protecting the interests of both the minority and the majority.

[Full text \(pdf\) >](#)

**Hansson, M.G., Combining efficiency and concerns about integrity when using human biobanks, Studies in History and Philosophy of the Biological and Biomedical Sciences, 2006;37:520-532.**

**Abstract:** In the debate about human bio-sampling the interests of patients and other sample donors are believed to stand against the interests of scientists and of their freedom of research. Scientists want efficient access to and use of human biological samples. Patients and other donors of blood or tissue materials want protection of their integrity. This dichotomy is reflected in the Swedish law on biobanks, which came into effect January 1st 2003. In this article I argue that if the basic interest of scientists using human biological samples is in increasing knowledge and developing better treatments, and if the concept “integrity” is properly understood, then sample donors should also be interested in promotion of efficiency as well as in the protection of their integrity. The basic premise of this argument is that donors of samples have interests related to the donation and use of samples as well as to the use of the results of the research, i.e., new medical products and treatments. They have a role both as donors or participants in research and as end-users of the research. I conclude that if i) access to information acquired through biobank research is strictly limited to researchers, ii) the information is protected by secrecy safeguards through coding and iii) the procedures governing the research are open to public and democratic control, then most research using human biobanks may be carried out on the basis of making general information available when collecting biological samples, without further contact with participants.

**Hansson, M.G., Dillner, J., Bartram, C.R., Carlsson, J., Helgesson, G., Should donors be allowed to give broad consent to future biobank research?, *Lancet Oncology* 2006;7:266-69.**

**Abstract:** Large international biobank studies can make significant contributions by validating the biological significance of previous research and detecting previously unknown causes of disease. However, there is a risk that too strict regulations for patient consent and that discrepancies in national policies on informed consent will hinder progress. It is therefore essential to establish a common ground for ethical review of biobank research. In this paper broad consent is defined on a scale between strictly specified and blanket consent. Future research includes that which may not be planned or even conceptualized when consent is obtained. It is concluded that broad and future consents are ethically recommendable for biobank research on the conditions that i) personal information related to the research is safely handled, ii) donors of biological samples are granted the right to withdraw consent and, iii) new research studies or changes regarding the legal or ethical authority of a biobank are subject to approval by an ethical review board.

[Link to full text >](#)

**Eriksson, S. & Helgesson, G., Potential harms, anonymization, and the right to withdraw consent to biobank research, *European Journal of Human Genetics* 2005;13:1071-1076.**

**Abstract:** This paper discusses the potential harms involved in biobank research and how ethical review, informed consent, withdrawals, and anonymization of samples should be handled in the light of these harms. There is less risk involved in biobank research than in human subject research; it should therefore be treated differently. In our view, anonymization should not be an automatically permissible response to requests for withdrawal. Nor should a request for withdrawal necessarily stop research on identifiable samples. Apart from not being particularly appropriate for protecting the interests of individuals, anonymization of samples has a negative impact on research. We suggest that the current view on withdrawal from research, supported by the Declaration of Helsinki and subsequent ethical guidelines, be abandoned in the context of biobank research and be replaced by an approach inspired by the Nuremberg Code. This approach requires those wishing to withdraw their samples from research to present sufficient reason for doing so. Our interpretation of 'sufficient reason' includes all those involving genuine, deeply felt concerns that are not based on misconceptions. Still, this underlines the fact that we all share a responsibility for health research and that no one should take withdrawal from biobank research lightly.

[Pubmed listing >](#)

**Eriksson S. & Helgesson, G., Keep people informed or leave them alone? A suggested tool for identifying research participants who rightly want only limited information, *Journal of Medical Ethics* 2005;31:674-678.**

**Abstract:** People taking part in research vary in the extent to which they understand information concerning their participation. Since they may choose to limit the time and effort spent on such information, lack of understanding is not necessarily an ethical problem.

Researchers who notice a lack of understanding are in the quandary of not knowing whether this is due to flaws in the information process or to participants' deliberate choices. We argue that the two explanations call for different responses. A tool for identifying those research participants who want limited information is presented. This consists of a restricted number of questions about trust in and appraisal of research, priority of time and privacy, and perception of a duty to participate. It is argued that an important group of participants who purposely lack understanding of the study can be identified with this tool. Some limitations to this approach are also discussed.

[Pubmed listing >](#)

**Hansson, M.G., Building on relationships of trust in biobank research, *Journal of Medical Ethics* 2005;31:415-418.**

**Abstract:** Trust among current and future patients is essential for the success of biobank research. The submission of an informed consent is an act of trust by a patient or a research subject, but a strict application of the rule of informed consent may not be sensitive to the multiplicity of patient interests at stake, and could thus be detrimental to trust. According to a recently proposed law on “Genetic Integrity” in Sweden, third parties will be prohibited to request or seek genetic information about an individual. Cumbersome restrictions on research may be lifted, thus creating a more favorable climate for medical research.

[Abstract and link to full text >](#)

**Helgesson G, Ludvigsson J, Gustafsson Stolt U., How to handle informed consent in longitudinal studies when participants have limited understanding of the study, *Journal of Medical Ethics* 2005;31:670-673.**

**Abstract:** Empirical findings from a Swedish longitudinal screening study show that many of the research subjects had a limited understanding of the study. Nevertheless they were satisfied with the understanding they had and found it sufficient for informed continued participation. Were they wrong? In this paper, it is argued that the kind of understanding that is morally required depends partly on the kind of understanding on which the research subjects want to base their decisions, and partly on what kind of knowledge they lack. Researchers must ensure that the information process is not flawed and that participants receive the information they want. To achieve this, new information efforts may be needed. Researchers must also ensure that research subjects have knowledge about aspects of importance to them. Lack of understanding may, however, be the result of conscious choices by research subjects to disregard some of the information because it is not important to them. Such choices should normally be respected.

[Full text \(free\) >](#)

**Helgesson G, Johnsson L. The right to withdraw consent to research on biobank samples, *Medicine, Health Care and Philosophy* 2005;8:315-321.**

**Abstract:** Ethical guidelines commonly state that research subjects should have a right to withdraw consent to participate. According to the guidelines we have studied, this right applies also to research on biological samples. However, research conducted on human subjects themselves differs in important respects from research on biological samples. It is therefore not obvious that the same rights should be granted research participants in the two cases. This paper investigates arguments for and against granting a right to withdraw consent to research on biobank samples. We conclude that (1) there are no explicit arguments for such a right in the guidelines we have studied, (2) the arguments against such a right are inconclusive, (3) considerations of autonomy, privacy, personal integrity, and trust in medical research provide sufficient reasons for granting a right to withdraw consent to research on biobank samples, (4) in certain cases, research participants should be allowed to waive this right.

[Abstract and link to full text >](#)

**Helgesson G., Children, longitudinal studies, and informed consent, *Medicine, Health Care and Philosophy* 2005;8:307-313.**

**Abstract:** This paper deals with ethical issues of particular relevance to longitudinal research involving children. First some general problems concerning information and lack of understanding are discussed. Thereafter focus is shifted to issues concerning information and consent procedures in studies that include young children growing up to become autonomous persons while the project still runs. Some of the questions raised are: When is it right to include children in longitudinal studies? Is an approval from the child needed? How should information to children be handled? A general point stressed is that autonomy considerations underline the importance of adjusting the information given to meet demands. A "presumption of competence" may be needed in research involving children, in order to pay their views sufficient attention.

[Pubmed listing >](#)

**Kettis Lindblad, Å., Ring, L., Viberth, E., Hansson, MG., Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think? *Eur J Pub Health*, 2006;16:433-440.**

**Abstract:** The aim of this study was to identify perceptions of the general public regarding research involving human tissues; to assess the public's willingness to donate samples to biobanks; and to identify factors associated with the willingness to donate samples. Methods: Cross-sectional survey. Postal questionnaires to a random sample of the general public in Sweden, 18–80 years of age (n 1/4 6000) in October 2002 (response rate 49.4%; n 1/4 2928). Results: A majority of the respondents had a positive attitude towards genetic research. Their trust in authorities' capability to evaluate the risks and benefits of genetic research varied. Individual university/hospital-based researchers received the greatest trust, while the county councils (health care providers), and the Swedish Parliament received the lowest trust. Most

respondents (86.0%) would donate a linked blood sample for research purposes. Another 3.0% would provide an anonymous sample. In total, 78% of the respondents would agree to both donation and storage. The most common motive was benefit of future patients. The majority was indifferent to the funding source for the research and would delegate this judgment to the research ethics committee. After adjusting for covariates, those more likely to donate a sample were middle-aged, had children, had personal experience of genetic disease, were blood donors, had a positive attitude toward genetic research, and had trust in experts/institutions. Conclusions: The majority of the general public is willing to donate a sample to a biobank. The willingness is mainly driven by altruism, and depends on the public being well-informed and having trust in experts and institutions.

[Abstract and link to full text >](#)

**Eriksson, Stefan, Should results from genetic research be returned to research subjects and their biological relatives? TRAMES – A Journal of the Humanities and Social Sciences, special issue on Human genetic databases: ethical, legal and social issues, 2004;8(1-2):46–62.**

**Abstract:** This paper addresses the question of whether to return information about disease and hereditary dispositions, resulting from research, including information that not only affects the research subjects but is also of interest to their biological relatives. An important prerequisite for a return is that results meet strong quality requirements. Moreover, the arguments in favor of a contact should outweigh those against it. When there is a moral demand to inform biological relatives, subjects themselves typically act as informants. If subjects are in doubt as to whether a contact is required, the investigators themselves must make a judgment. If they feel it is indeed necessary, they should try to strengthen subjects' autonomy and encourage them to take responsibility. It is argued that this is neither a paternalistic line of action, nor does it undermine the autonomy of research subjects and their relatives.

**Hansson, MG & Levin, M (eds), Biobanks as Resources for Health, Uppsala University, 2003, ISBN 91-506-1659-6**

**Abstract:** The potential benefits of biomedicine and biotechnology are considerable, but this is also an area of science and medicine that is sometimes found controversial. Decisions made by scientists, by health care professionals and by policymakers must be well informed and based on knowledge and sound research. Legal experts concerned with public law and intellectual property rights, philosophers and social pharmacists have been collaborating with geneticists, pathologists, and doctors in several research projects in order to seek the kind of biobank management that would satisfy the interests of both the research community and the general public as regards new medicines and forms of treatment, whilst protecting the integrity of the individual. A summary of that research is presented in this book.

**Hansson, M.G. (ed.), The Use of Human Biobanks. Ethical, Social, Economical and Legal Aspects. Report I, Uppsala University, 2001, ISBN 91-506-1472-X.**

**Abstract:** Human biological material – such as cells collected in research projects, biopsy specimens obtained for diagnostic purposes, and organs removed during surgery – has become vital for research in biomedicine and biotechnology. The main purpose of this project is to propose ethical and legal guidelines so that the research, diagnostic and treatment value of these biobanks may be acknowledged without violating the integrity of individual research subjects and patients. As a working definition, “biobanks” are collections of human biological material within the health care system and the medical sciences. Both privately and publicly financed biobanks are included. Within a multi-disciplinary research format, ethical, economical, social and legal problems associated with the use of human biological material are analysed.

**Hansson, M.G., Balancing the quality of consent, Journal of Medical Ethics 1998;24:182-187.**

**Abstract:** The rule that one must obtain informed consent is well established in medical ethics and an intrinsic part of clinical practice and of research in biomedicine. However, there is a tendency that the rule today is being applied too rigidly and with too little sensitivity to the values that are at stake in connection with different kinds of research protocols. It is here argued that the quality of consent needs to be balanced against variables such as degree of confidentiality and importance of values at stake, in order to be ethically acceptable. Appropriate information and consent procedures should be adjusted accordingly. Three levels are suggested, ranging from extensively informed consent with both written and oral information, through informed refusal with only a limited amount of information given to, at the other end of the scale, just making relevant information available.

[Abstract and link to full text >](#)

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