



THE DANISH
COUNCIL OF
ETHICS

*Research with health data and
biological material in Denmark*
Statement



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biological material in Denmark*
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**Research with health data and biological
material in Denmark**

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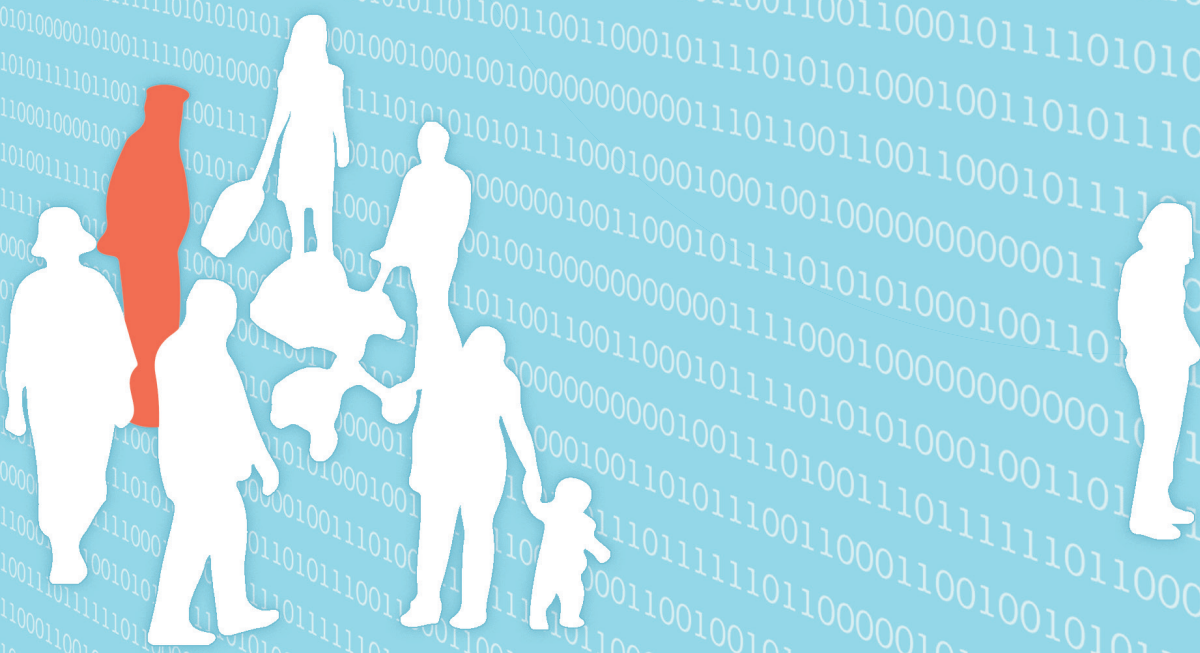
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Preface

This statement has been prepared by a working group under the Danish Council of Ethics consisting of Thomas Ploug (Chairman), Jacob Birkler, Gorm Greisen, Lise Von Seelen, Poul Jaszczak and Mickey Gjerris.

The work commenced in April 2014. The statement has been reviewed and adopted by the Danish Council of Ethics at meetings held in March and April 2015.

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May 2015

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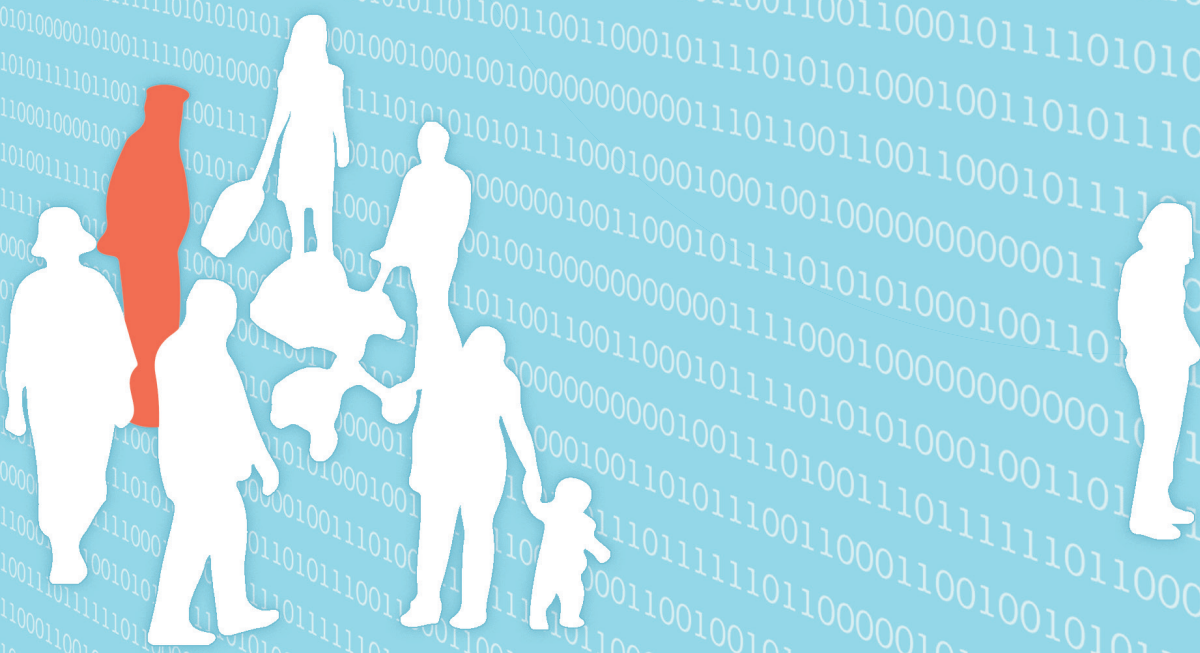
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Research with health data and biological material in Denmark

Great research potential of health data and biological material from the Danes

Health research enhances the possibilities of leading a good life with or without disease. Successive governments in Denmark have therefore been dedicated to ensuring optimal condition for health research.

These years, interest is not least centering on the research value of the comprehensive collections of health data (data registers) and biological material (biobanks) that have accumulated for decades as part of the healthcare sector's activities and in association with research (see examples in the box below).

A large proportion of the Danish population's health data and biological material is stored at the SSI (State Serum Institute). During the course of one year, the SSI will have distributed information about almost every Dane. The data of certain patient types could be used repeatedly each year. Mostly it occurs without the consent of those involved, and presumably only very few people know about it. According to the SSI, at least 400 data extracts were made in 2014 for research and statistical purposes in hospitals, universities or in companies, ministries and patient organisations, etc. To this should be added the extracts made by Statistics Denmark, which also maintains registers with health data. One single extract may cover information about several thousand Danes.

The collection and use of health data are natural elements in the activities of the health sector, which could include data about treatments, diagnoses, length of inpatient stays, drug benefits and much more. To ensure the continual improvement of healthcare services, it is necessary to collect and analyse previous care pathways, for example to identify treatments that are effective and treatments that are ineffective or perhaps even harmful. Similarly, samples of human biological material are collected from patients, e.g. blood samples or biopsies of tumours for diagnostic purposes.

While the collection of data and tissues can be said to serve a primary purpose of improving the treatment for the individual patients, the resulting accumulations of data and tissues have moreover proven to hold immense research value. This secondary use of health data also benefits the treatment of patients, although in a less direct manner. The direct purpose of research is rather to improve the scientific evidence for future treatment and prevention than to influence the treatment of patients here and now.

By comparing prescription data of a certain medicine with data on the health of patients who have been prescribed this medicine, it is possible to outline the medicine's benefits and adverse effects. Perhaps, it is discovered that a medicine prescribed for a certain condition also has a beneficial effect on another type of illness. This could potentially improve the treatment of another disease, a discovery often requiring extensive research.

By examining patient genetic material, it is moreover possible to explain why some people benefit from a medicine while others do not. Such investigations could for example be based on surplus material from blood samples taken for diagnostic or other purposes. There are high hopes that analyses of individual drug response in the long term can limit unnecessary drug consumption and adverse reactions. This is the ambition of so-called precision medicine.

It is widely agreed that the use of data and tissues offers great potentials; The terms of reference for the national strategy on access to health data state that:¹

"(...) the Danish health data that are generated in the treatment of patients and administration of health services together with biobank material hold tremendous potential for research purposes and perspectives of growth. Denmark could therefore benefit highly from creating an improved enabling environment for research with electronic data and biobank data while ensuring that the Danish people can be safe and continue to have confidence in the research environment."

As with any other research area, there are evidently many diverse interests involved in health data and biobank research. For example, there are great political interests in fostering research that improves companies' opportunities to develop new treatments. This would thus increase jobs, tax revenues and other social assets in addition to raising the companies' earnings.

While there are many countries that show interests in establishing and doing research on health data and biobank material, it is widely held that the Danish collections of data and tissues have particularly high scientific value due to their specific completeness and comprehensiveness, etc. If such data volumes were to be collected from scratch, it would moreover be extremely time and cost-consuming. In this respect, Danish health research enjoys a competitive advantage.

Ethical dilemmas

Health research is affected by fundamentally contrasting values and thus ethical dilemmas. So, no matter how the health research area is regulated, there will be advantages and disadvantages.

Commenting on the authorities' extensive distribution of health data, Minister for Health Mr. Nick Hækkerup said to Danish Jyllandsposten in June 2014:²

1 Terms of Reference – National Strategy for Access to Health Data, 25 February 2014 (Danish title: Kommissorium - National strategi for adgang til sundhedsdata)

2 Nick Hækkerup about data extracts: *Balancing trust and research* (Danish title: *Balance mellem tillid og forskning*), Danish newspaper, Jyllandsposten, 16 June 2014.

I won't deny that this is a difficult case. It is a dilemma; on the one hand, we must ensure that the Danish people can trust that their health data are handled with utmost confidentiality and do not fall into the wrong hands (...) On the other, we all have an obvious interest in allowing researchers to access health data so they can increase their knowledge about what causes for example specific cancer diseases.

Using the word dilemma does not necessarily mean that all choices from an ethical point of view can be regarded as equally acceptable. There are limits to what you can put individual research participants through, regardless of how few they are or how beneficial to society a given research project would be. Research legislation confers a number of rights on research participants/citizens, in the form of individual protection measures, such as the right of self-determination. The Danish act that regulates the scientific processing of health scientific research projects reflects this in overall terms:³

The rights, safety and well-being of research participants come before scientific and public interests in creating opportunities to obtain new evidence or to investigate available evidence that may justify the completion of the research project.

Correspondingly, the Danish Act on Processing of Personal Data stipulates that sensitive personal data may only be processed for statistical or scientific purposes "of significant public importance".⁴ Both acts promote the balancing of a number of concerns, including privacy, self-determination and public benefits.

Even though the wordings of the two acts may leave the impression of a simple conflict between individual interests and public interests, it is much more complex. Many citizens become research participants because they want to further research; conversely, research has an interest in ensuring the well-being and trust of research participants.

As this statement will show, the balance between various concerns is subject to both changing premises and changing conclusions, and it calls for an ethical debate about research with health data and biological material. In particular, a line of scandals involving leakage, unlawful collection and hacking of registries holding sensitive personal data have raised awareness in the public.

The current challenges of safeguarding citizens' privacy should be seen in the context of these years' biotechnological and information technological revolutions. As a result, increasing volumes of health data are being collected about the Danish people, all the while it is becoming increasingly difficult to secure these data from unauthorised access.

3 The Danish Act on Research Ethics Review of Health Research Projects establishes the framework for the research ethical review of health research projects involving human beings and human tissues, including biobanks.

4 The Danish Act on Processing of Personal Data regulates the processing of personal data wholly or partly by automatic means, and the processing otherwise than by automatic means of personal data which form part of a filing system or are intended to form part of a filing system, including biobanks.

Statement content

The statement revolves around four values that are fundamental in health research. Each value is introduced and put into perspective, serving as a basis for the Danish Council of Ethics' recommendations:

1. Benefit and solidarity
2. Privacy
3. Trust
4. Self-determination
5. Recommendations of the Danish Council of Ethics

Read more...

In the electronic version of the Danish version of the statement, it is possible to navigate via links to further descriptions of central themes and concepts. These are described in three working papers on the factual, ethical and legal aspects of research with health data and biobanks, which form part of the investigative work on which this statement is based. The three working papers, which also include references, can be found at www.etiskraad.dk (in Danish only).

Delimitation

This opinion covers the use of health data and biobanks for *research purposes*. It does not cover, the ethical questions associated with the use of health data for *clinical* purposes, which are addressed in the Danish Council of Ethics' report on the Shared Medication Record (2010). Nor does the opinion cover the use of health data and biobanks for *administrative* purposes or *quality* control, in so far as quality control means an activity whereby:

- data are shared only within the relevant area of specialty;
- data at individual-level are processed only when needed;
- access to data is limited as far as possible;
- the use of data is considered to be of direct benefit to the quality of treatment at the concerned treatment facility;
- the intention is not to publish the work as research.

Examples of health data registers

Medical records. Data on the individual citizen's treatments, diagnoses and consultations, etc. kept by the patient's general practitioner, at the hospital, etc.

Registers with data from clinical trials. A comprehensive database with data from clinical trials of medicinal products is being developed at EU level.

The National Health Registers. The SSI collects data about the population's health, e.g. about the citizens' use of healthcare services, vaccinations, causes of death, drug consumption, prevalence of cancer and diabetes, etc.

Research registers. The supercomputer *Computerome* at DTU, Technical University of Denmark, (launched in 2014) aims to include large volumes of genetic data from Danish citizens. Its capacity is 4-fold the total capacity of US research libraries.

Secondary data from previous and ongoing studies. Data from previous research can often be reused in new research, and data can be linked across studies. This could be unprocessed biological data (test results, genetic data, etc.), questionnaire replies, etc.

Examples of biobanks

PKU Biobank. Heel prick blood sample from all newborns since 1982. Approx. 2 million samples.

The Patobank (pathology data bank). Contains approx. 14 million tissue samples, the oldest ones are about 50 years old. Receives approx. 750,000 new samples annually from Denmark's 14 pathological departments.

Capital Region Biobank: Surplus material from the region's blood samples.

SSI's diagnostic samples. Surplus material from blood samples submitted for infectious disease testing. Approx. 4 million samples, some more than 100 years old.

Danish Cancer Biobank. Tissues and blood material as well as various health data.

"Freezers" with material from individual research projects, e.g. from PhD projects. There is no overview, but they are said to be many.

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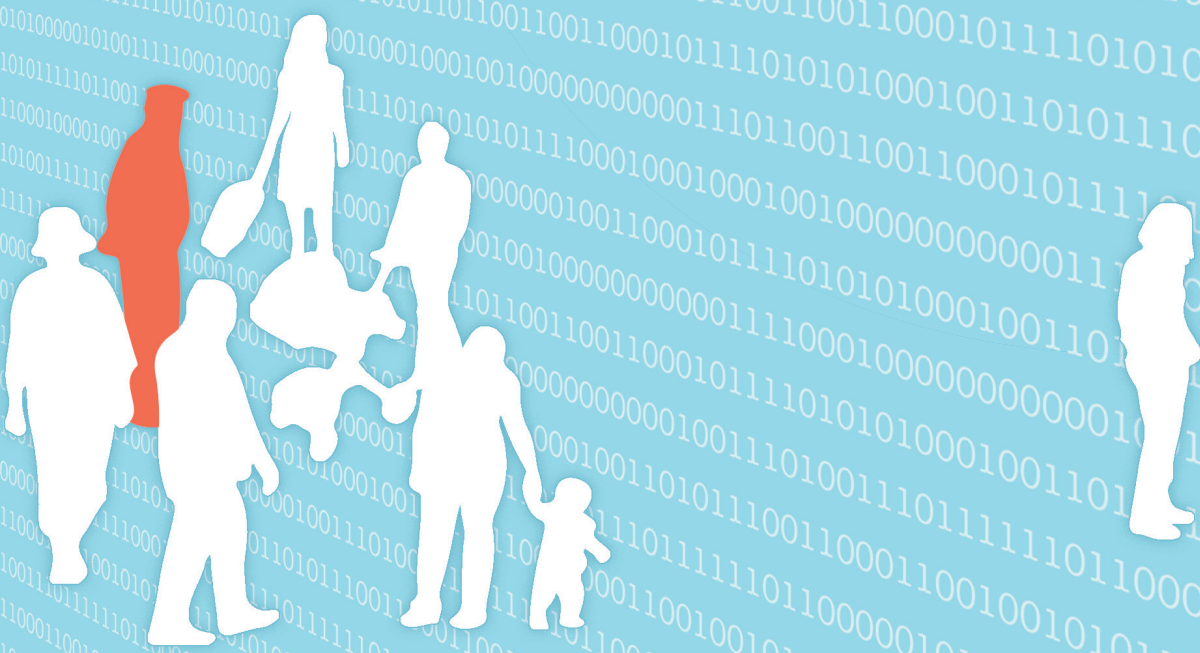
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1. Benefit and solidarity

Background

The primary public benefit of promoting health research in Denmark is that it will lead to improved treatment of patients in Denmark and elsewhere, and that it will strengthen Danish research and its ties to international research.

In other words, research that continually improves the available knowledge of disease causes will save lives and improve quality of life. When researchers can work with increasingly better data, the quality of produced evidence will increase accordingly, all other things being equal.

Health research saves lives: Suspicion about MMR vaccine refuted

In 1998, a study was published which suggested a causal link between the MMR vaccine and autism. Although the study was later proved to be fraudulent, it nonetheless meant that many parents chose not to vaccinate their children. As a result thereof, we are these days witnessing measles epidemics in several European countries and in the USA with fatal outcomes. It is happening even though the disease is easy to prevent by vaccination and was almost eliminated in the 1990s. A Danish study, which was based on Danish health registers, contributed to refuting the suspicion about autism as an adverse reaction to the vaccine. Generally, it should be presumed that thorough evidence will improve the quality of the health sector's recommendations and services.

Moreover, health research has an economic potential. The terms of reference of *the National Strategy for Access to Health Data* (2014) state the following:

The purpose of the strategy is to create an even better basis for health research in Denmark for both public and private operators. In addition, the strategy is to create a better basis for collaboration with the business sector in the area of research and development of new solutions. Both elements can contribute to creating a better health sector, growth and jobs in Denmark.

Thus, the purpose of promoting access to the Danish population's health data is both to further research and treatment possibilities and to generate growth and jobs. But what about the citizens who supply the data from which all these benefits are to grow? In connection with a bill proposed in March 2014 it is noted that:⁵

According to the government, participation in research of relevance to society is part of being a citizen committed to society, and it helps strengthening our sense of community.

So, the political stance is that the citizens' participation in research is an act of solidarity with public benefit. An appeal to or expectation of citizens to participate in research is, in other words, founded in the values of *solidarity* and *benefit*.

Ethical arguments in favour of fostering solidarity and benefit

Benefit

Pure considerations of benefit could significantly justify that access to research with human tissues and data should be allowed. Considerations of benefit are based solely on how much benefit or utility value a given action or a given societal practice would bring with it. According to some ethical theories – e.g. utilitarianism – there is a moral duty in many cases to take actions or implement practises that combined carry great utility value even if the given practice has considerable negative consequences for some of those involved. The benefits for some may in some cases outweigh the negative consequences for others. This not least applies if the disadvantages are small, while the benefits are great.

It could be argued that this is exactly the case with research in health data and biological material. Most often, the disadvantages and risks the individual citizen is exposed to are relatively small compared to the potential beneficial outcome of the research in the long term, not only in Denmark, but also globally.

The conclusion to be drawn from weighing up all advantages and disadvantages would mostly depend on a number of aspects which often are not easy to gain insight into. In biobank research, it would for example be relevant to know something about the following aspects:

- How will patient treatment be impacted by research with health data and biological material?
- How big is the risk of data leakage, and how burdensome would any such leakage be?
- Will distrust develop in the long term if the right to informed consent is limited?
- What will be the overall impact on Danish economy from easy access to biobank research – and who will enjoy these economic benefits?

5 *Explanatory notes to the bill.* Bill no. L 110, 2013/1, Act to amend the Danish Act on the Civil Registration System.

Solidarity

Solidarity is a value which can be said to penetrate large sections of society's basic institutions, including not least the public healthcare system. If the health sector and society as a whole are based on a principle of solidarity, then perhaps it might seem obvious to also require a certain degree of solidarity from those who enjoy the benefits of the system.

If it is expected that health data and biobank research should benefit other patients and society as a whole, one could argue that the citizens at least should have a basic duty to let their tissues and data be included in research. Such duty could be disregarded if significant research risks are involved.

That some people enjoy the benefits of the system without being willing to contribute themselves does not necessarily mean that participation should be forced on them, but merely that it might be appropriate to express to them that participation is considered a valuable contribution.

It is more debatable if citizens should be obligated to promote activities designed to stimulate private companies' revenue potential as suggested by the government. Companies specifically are not expected to show solidarity with society, and so the mentioned mutuality is missing. Nonetheless, it is evident that companies contribute highly with goods that must be considered as more or less common, such as new treatments, jobs and tax revenues. From the perspective of solidarity, it would seem disloyal wanting to enjoy these benefits without wanting to promote the provision of them – even if it implies that additional private benefits are also generated. Admittedly, there could be reservations about promoting the development of public benefits in precisely this way; On the other hand, a democratic choice has been made deciding that drug development and other benefits are best achieved through private companies and financial incentives.

But all questions of solidarity in health data and biobank research are by no means solved. The solidarity considerations outlined above may propose that each citizen should to some degree contribute to the development of new treatments by making his or her data and biological material available to research. But there are obviously many loose ends when it comes to the extensiveness of demands that community can place on the individual. How burdensome can research be for participants and how big a risk can they be exposed to? Should participation be mandatory or voluntary? And to what degree can a citizen in one country be expected to show solidarity with citizens in another country?

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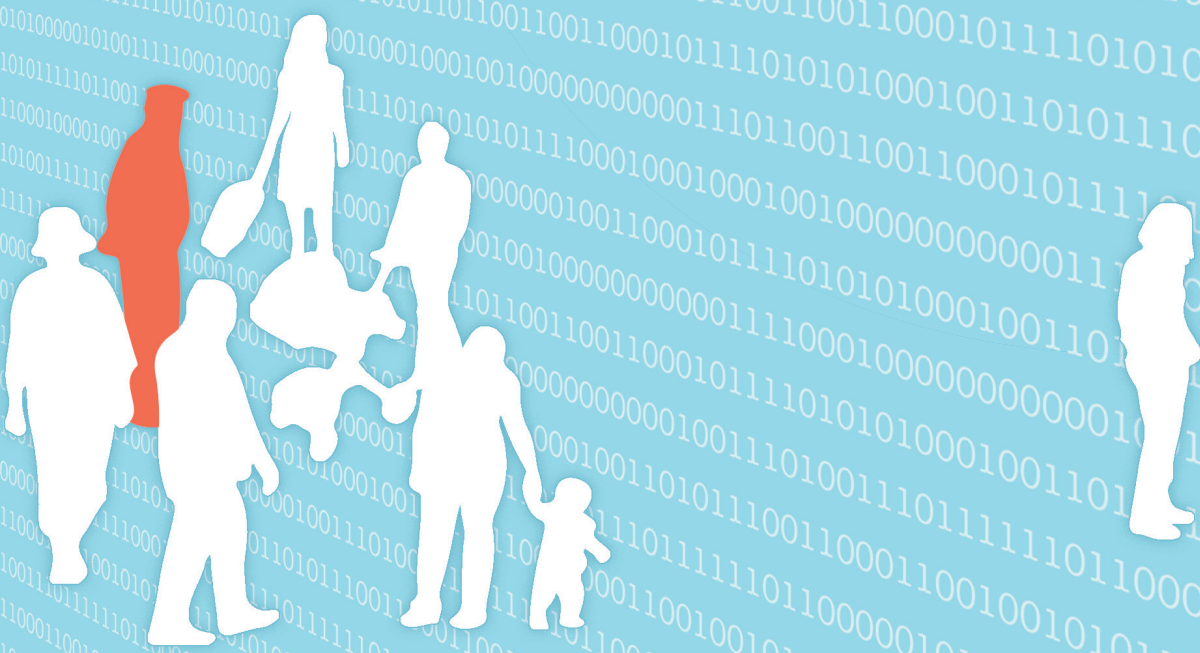
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2. Privacy

Background

Given the massive escalation of researchers' collection, exchange and use of health data and biological material and the increased access to data brought about by digitisation, the risk that sensitive information can be leaked has increased accordingly.

In only a few years, a number of cases in and outside Denmark have shown us that it can be a struggle to adequately safeguard the privacy of citizens. Among the most debated cases are:

- The CSC scandal: In **2012**, hackers obtained unnoticed access to information in the Danish Police's CPR Register (Civil Registration Register) and the Central Crime Register.
- Edward Snowden: In **2013**, the NSA employee managed to get out of one of the USA's most guarded institutions with extensive volumes of confidential information and thereby revealed massive surveillance activities.
- NETs/Se&Hør scandal: In **2014**, it was revealed that an employee from NETs was selling sensitive information about celebrities' credit card transactions to the weekly magazine Se&Hør.
- DAMD: In autumn **2014**, DR (Danish Broadcasting Corporation) uncovered how the Region of Southern Denmark in the context of the Danish General Practice Database (DAMD) for years had been unlawfully collecting confidential information about diagnoses made by physicians practising throughout Denmark for research and analysis purposes.
- In January **2015**, the Danish Data Protection Agency criticized the Central Denmark Region because considerable volumes of health data via the electronic patient record were available to an unnecessarily wide group of employees employed in the region.⁶

There are many circumstances of importance to the level of protection required for biological material and health data. These circumstances have changed significantly with the technological advances of recent years:

- Generally, the possibilities of re-identifying biological material or health data whose identifying information has been removed (e.g. through anonymisation, pseudonymisation or statistical processing) have increased.
- Health data predictivity (i.e. capability of data to predict future disease) has increased in response to rapid progression within examination of tissues and interpretation of

⁶ The Danish regions are responsible for running the hospitals

data. Currently, this is especially true for genetic data, but to varying and increasing degrees also to other bioinformatic data. Such health data can be considered as particularly sensitive.

50 anonymous citizens identified

It raised awareness in 2012 when a researcher was able to guess the identity of 50 persons from a larger group of anonymous citizens who had donated their genetic data for publication as part of a research project. He did so by searching for a number of different pieces of information available on the internet.

Ethical arguments in favour of protecting privacy

Autonomy and identity

In the western world, the individual's right to privacy is first and foremost justified in the right to decide your own personal life and thus to live an autonomous life. The concept of autonomy is here used to explain that it may constitute a *special* form of offence against a person if others have access to information about the person without this person having consented to such access. This special form of offence has to do with the individual's right to control his own identity.

The nature of many of the details that can be generated from biological material in biobanks or health data from a data register is such that it can decisively influence how a person is perceived. This could be information about genetic predispositions to disease, kinship, mental disorders, etc. The person behind this type of information could have obvious reasons to limit its disclosure, both to persons outside the health sector and employees in the health or research environment.

There is a narrow connection between an individual's identity and the information about the individual to which others have access. Most people find it important that there is a certain coherence between their self-perception and the perception formed by others. But, a person can find it difficult to maintain a specific self-perception if it is contradicted by the perception formed by other people. That person could feel "pigeonholed" or "branded" by persons who have had access to his or her sensitive health data.

Discrimination

If unauthorised persons acquire access to health data, the individuals from whom the information originates may also be pigeonholed in a more tangible manner. If the information is used to unreasonably discriminate against the person, it could have serious consequences for that person's possibilities of e.g. getting certain jobs, insurance, bank loans or other services which depend on an assessment of the individual's capability. Even though in some cases it is completely warranted to require that certain facts about the individual's health be given, e.g. in connection with insurance, there may be other

justified reasons why an individual would want to limit the dissemination of his or her sensitive health data.

Personal integrity and dignity

The right to privacy can also be justified in the notion that a person is entitled to have its innermost or most central core of its personality and body protected – *regardless* of whether such wish has been expressed. Some individuals such as small children or permanently incapacitated patients have no possibility of expressing their wishes. But it appears as obvious that they too have a right to privacy, regardless of whether or not they are able to understand the loss of privacy or experience the consequences as negative.

Perhaps personal integrity can best be defined as a physical and mental untouchable zone which the individual human being has a right to demand be respected. It could also be called a right to freedom from improper interference in the individual's personal affairs. The respect for human integrity is not conditional on personal intellectual capability, but should be seen as a fundamental respect for the basic and equal dignity and moral status which all human beings – regardless of mental capability – possess.

Confidentiality and trust

Confidentiality can be defined as a mechanism to protect and respect privacy. When a person gives information to another person "in confidence", he or she expects that the information given will not be made available to everyone. If the information is disclosed unduly to someone outside the narrow personal relation in which it was given, confidentiality has been breached with resulting invasion of privacy.

The degree to which a patient is willing to give personal information may vary from person to person, and it is very much a question of trust. Trust may be based on experience and depend on how the recipient of information has previously handled information given in confidence. But trust could also be based on institutional trust, i.e. confidence that a professional authority will handle trust correctly.

If a patient experiences lack of confidentiality, that patient will lose trust in the health sector. This could affect the patient's treatment situation or even impact the patient's decision on whether to contact the health services in the first place. If, for example, the patient has an infectious disease requiring treatment, the implications for society could be extensive if the patient does not seek treatment.

Balancing the concerns

How well can health information be protected?

As initially described, the loss of privacy within health research may in various ways place burdens on citizens and society. In the last couple of years, several cases have shown that it may be difficult to protect even highly secured or anonymised data.

The most common response to security breaches is an increase in data security, e.g. through encryption and stricter access and application rules. In the meantime, there are limits to how well data can be protected via such measures.

Data security inevitably depends on those who handle the data. Carelessness, errors and abuse can lead to data leakage.

In addition, data security requirements complicate research and could limit the beneficial output of the collected data. The request for increased data security is therefore far from unproblematic.

Can health data and biological material be anonymised?

Mulighederne for at re-identificere anonymiserede individer er som nævnt blevet større. As mentioned, the possibilities of re-identifying anonymised individuals have grown. In the vast majority of cases, it is hardly a problem that anonymity can be broken as doing so would normally require considerable resources and will. So, the actuality that anonymity can be broken hypothetically does not mean that data are considered as personally identifiable in the meaning of the law. It may nonetheless be difficult to make predictions about what possibilities of re-identification the future holds. The risk increases with the period of time data/tissues have been stored and with the number of people who gain access to them. The construction of registers and biobanks of a permanent nature and intensified sharing and usage can therefore be said to challenge the protection of privacy.

In special circumstances, there could even be strong interests in making the personal information of certain individuals available. We saw this in the NETs case, in which an employee sold information about celebrities' credit card transactions to the weekly magazine *Se&Hør*. In certain areas of the world, a grey market of so-called *data brokers* has developed over the past years. They make a living by collecting and reselling confidential information, e.g. for marketing purposes. In April 2015, it became known that the health data of 2,500 Danish diabetics could be bought from the American data merchant Exact Data. It is unclear how the company had acquired access.

In other words, it is possible to distinguish between different aspects of significance to the possibilities and needs of protecting the anonymity of citizens:⁷

- Most people find that it is more important to protect their data from disclosure to the ones they know (the so-called privacy set) than to strangers, e.g. a researcher in another city. For most people the privacy set includes a limited number of people, though for celebrities or public figures there could be many more.
- Individuals can be more or less anonymous depending on the possibilities of narrowing the group to which they are likely to belong by means of their data/tissues. The detail "present member of parliament" would in Denmark narrow the so-called anonymity set to 179 people.
- The protection considerations also depend on who the potential viewer is – is it just anybody, a nosy neighbour, or someone with malicious intentions.

All these circumstances change over time in step with societal developments.

⁷ Read more thereon in: *The collection, linking and use of data in biomedical research and health care: ethical issues*. Nuffield Council of Bioethics, 2015.

Are health data adequately protected?

As far as can be determined, we have seen no examples of health data loss in research which have caused direct harm to citizens in Denmark despite the thousands of analyses and data transfers being performed every day.

But there are signs that generally quite many errors and breaches of data processing rules occur, the result being that sensitive health data are unduly made available to unauthorised individuals. This could be of indirect inconvenience to citizens if confidence in research and the healthcare sector is compromised.

Security breaches could happen if researchers and others are not sufficiently familiar with the data processing rules or take them too lightly. To all appearances, it happens from time to time that researchers fail to delete data or destruct biological material after use. There is no overview of the extent of security breaches in Danish research, but, generally, the number of security breaches is rising.

A number of experts which the Danish Council of Ethics has consulted leave the impression that generally the data security culture has not moved with the developments in IT and biotechnology which put the protection of privacy under pressure.

Against this background, it could be doubted whether the privacy of citizens in future will be as well protected as in past. It might not necessarily be a problem as long as many research participants are willing to run a small limited risk in the name of science. But there could be arguments in favour of strengthening the requirement for obtaining explicit consent with respect to research with human tissues and particularly sensitive data.

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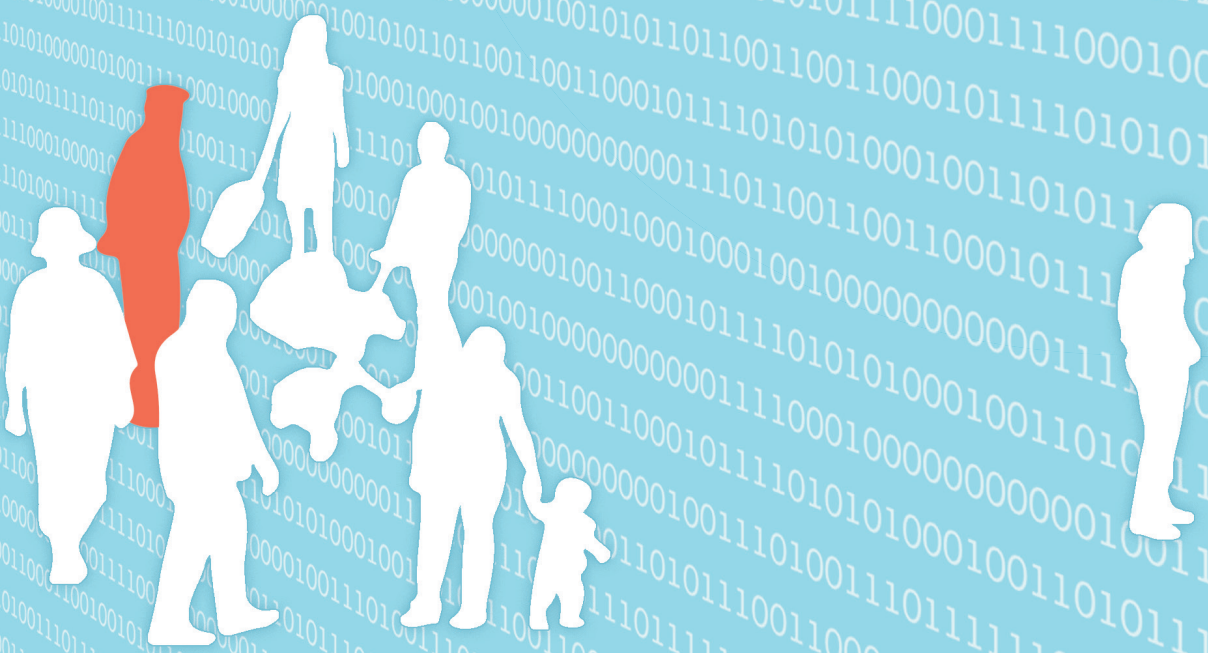
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3. Trust

Background

The Danish people's trust in research is often highlighted as an asset giving Danish researchers unique research possibilities.

Conversely, the British Government's current plans of making its citizens' health data available to research – the so-called *care.data* programme – backfired in 2014 in response to public distrust. At the time of writing, one year after scheduled launch, no one has dared even to implement scaled-down tests of the system. According to observers, the safeguarding of citizens' privacy had not been sufficiently dealt with.

Ethical arguments in favour of building trust

Trust as a life-quality and as a quality in relationships

Trust is a quality in its own right. Trust is also important because distrust causes insecurity and indicates a feeling of lack of respect.

Trust emerges in relations which foster mutuality and which are ethically oriented in the sense that *both* parties in the relation assume ethical obligations.

The ethical dimension of the relation implies that the parties will then build up certain mutual expectations that are value-based and may cover elements such as competence, sincerity, empathy, altruism, kindness, fairness and reliability.

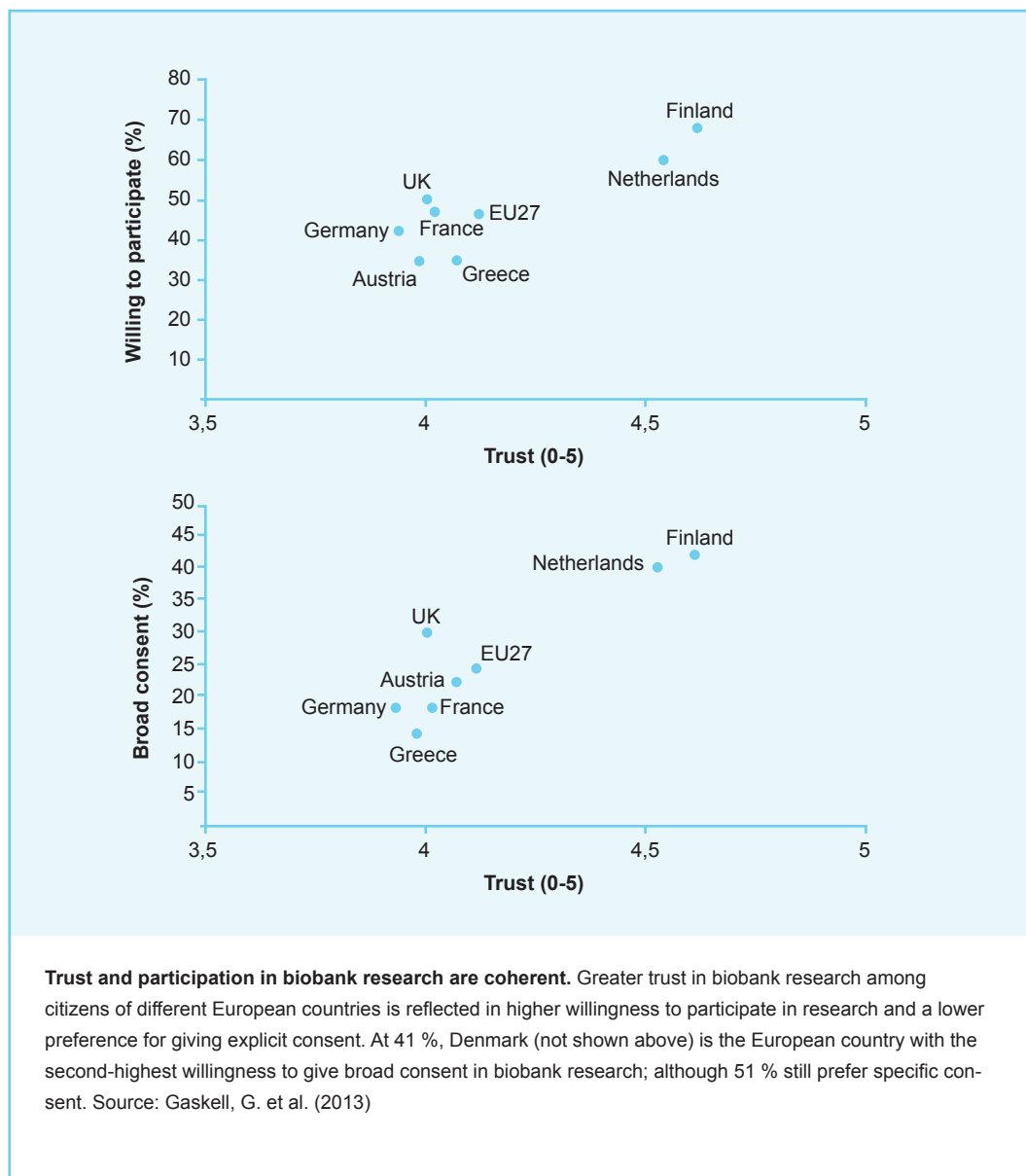
Expectations for research are likely to vary between citizens depending on numerous circumstances, e.g. the type of data or tissues, the collection situation and the purpose or outcomes of the research. Factors of religion, historical experience and culture are also influential. Therefore, the expectations and concerns raised by people of different nationality could vary greatly across Europe.

If it is true that trust has an ethical dimension, it is not tenable in the long run to have a purely instrumental relationship with the citizens whose tissues and data are used in research. The values of citizens and their diverse perspectives on participation should in some way or other be accommodated in order to call it an ethically-based relation.

In this connection it should be mentioned that trust can be built in the relationship between individuals and by virtue of the values on which a given institution is generally founded, such as solidarity or incorruptibility.

Trust as a precondition for research

The Danish people are among the nationalities in Europe most willing to give information for use in biobank research. Surveys show that greater trust make citizens more inclined to participate in biobank research and less concerned with giving consent. In other words, the trust of citizens is of great importance to researchers' possibilities of delivering high-quality research.



Balancing the concerns

The trust of citizens cannot be taken for granted. Among other things, it is conditional on the continued mutual respect between research and research participants. Trust is related to the research participants' diverse interests, perceptions and expectations and to each participant's own specific experience with research participation. Not least could it be

conditional on how the authorities protect or historically have protected the concerns of research participants and patients.

If trust in research is lost, it will obviously have serious consequences not just for health data and biobank research, but also for Danish research itself – and for citizens and the health sector.

Trust can both be related to the conceptions and expectations that current citizens place on research and to the trust-building and protective structures and principles that historically have been introduced to tackle crises of distrust, etc. One such example is the principle of transparency in public administration.

Probably, the ethical importance and trust-building significance of both informed consent and protection of privacy are to some degree perceived as less evident than before. The protection of the individual, as we know it today, is to some extent based on the 20th century's incidents with serious abuse of research participants, surveillance of political opponents during the cold war, etc.

Privacy and self-determination

Surveys confirm that privacy and consent in biobank research are important across the European countries. To our knowledge, there are no surveys that specifically investigate the Danish citizens' opinion and views on the collection and use of health data.

It could be feared that each time it emerges that authorities, researchers or hospitals have experienced data breaches – as we have seen several times in the past few years – the trust of citizens will erode. Moreover, the use of biological material without consent seems to clash with many citizens' expectations.

Consent practices may affect trust in the health sector, because many of the health data and biological samples that are being researched are collected at hospitals or by general practitioners. Over the past couple of years, general practitioners have voiced concerns that the use of confidential patient information for research and administrative purposes without consent is undermining patient trust.

Solidarity, benefit and commercialisation

Research participants generally do not think of their relationship with biobanks as purely altruistic, but rather as a sort of gift relationship that confers certain requirements and obligations. For example, many people expect that their "sacrifice" will result in common goods rather than commercial goods in addition to potentially certain personal goods, such as access to special treatment offers or diagnostic information. There are concerns that commercial operators do not handle data as responsibly as public operators. Having said that, patient organisations generally have decisively more confidence in private research.

With this in mind, it is not surprising that the media's coverage of security breaches have prompted concerns that the Danes' health data might be "sold" to companies.

Changing governments' declared objectives of translating the Danish population's health data and biological material into economic growth could in this respect easily be colliding with the expectations of research participants.

It should be noted, however, that "commercial exploitation" of health data and tissues could mean a variety of things. Institutions like the SSI and Statistics Denmark are only permitted to cover their expenses of data distribution and thus are not allowed to sell data for commercial gain. Researchers in private companies have access to data on the same terms as public researchers.

Transparency

Transparency is considered a fundamental principle in the relationship between public authorities and citizens.

Surveys show that many citizens want information about the purpose of biobank research, what is permitted, who are involved and the results derived from the research. Thus, it seems that transparency is generally considered to be an important value in biobank research.

Control

Negligence by public authorities can weaken trust in certain groups or activities.

In light of this, it is worth noting that several of the experts whom the Danish Council of Ethics has consulted see the Danish Data Protection Agency's possibilities of performing adequate supervisory control as being heavily constrained by lack of resources. The penalties for security breaches are moreover described as weak. Current developments in the provision and processing of data, including not least health data, should be expected to entail still higher demands.

4. Self-determination

Background

Fundamentally, research involves a multitude of potentially conflicting interests, including the wishes and well-being of research participants, research itself, commercial objectives, researchers' careers, etc. The presence of conflicting interests is a fundamental premise of research legislation.

Historically, informed consent emerged from clear incidents where the rights of research participants had been infringed, and informed consent was therefore introduced to establish a right that research participants could exercise to protect themselves.

Citizens' self-determination is also protected in other ways, e.g. via the legislation's possibility to withdraw from research (*opt out*) or the right to have data adjusted or stored tissues handed out.

As society does not want to limit research unduly, the regard for citizens' self-determination has been adjusted regularly in line with the estimated need for protection. Informed consent became a statutory requirement in 1992. Certain exemptions have since been implemented in a number of areas.

- *Exemption from informed consent in biobank research*
Since 2004, the ethics committees have been permitted to grant exemption from the statutory requirement for informed consent in biobank research. Today, it has become common practice that exemption from statutory consent is granted.
- *Anonymous biobank research and register research exempt from research ethics review and consent requirement*
Research does not require notification to the ethics committees and mostly not consent if involving anonymous biological material (since 2011) or health data (since 2003).

Ethical arguments in favour of citizens' right to self-determination

Right to protection from risk

Basically, the informed consent requirement is stronger within research than it is within the treatment services of the health sector. Whereas treatment is often initiated based on verbal consent, participation in research is generally based on explicit and written informed consent for each specific research project.

The reason that research projects are subject to stronger consent requirements than treatment services is that the research purpose is not in the participant's interest, but research that serves a multitude of interests. Research may involve risks for research participants that cannot be assumed to be outweighed by personal benefits as would be the case in the context of treatment.

Traditionally, the statutory requirement for informed consent and research ethics review in health data and biobank research have largely been justified on the basis of an assessment of whether research would expose citizens to physical strain.

Whereas the legislation focuses on physical strain, citizens may as mentioned be burdened in many other ways, which have become significantly more apparent as a result of the recent years' societal and technological developments:

- Protecting the privacy of citizens has come under pressure as a result of new ways to break anonymity and issues with data security.
- Health research increasingly provides uncertain information about genetic predispositions to disease, etc. of questionable clinical relevance and desirability.
- The dissemination of and research with data considered as confidential could be experienced as uncomfortable and lead to a loss of trust in the physicians or researchers who collected the data.

All in all, it is becoming increasingly difficult to argue that research with health data and biobank material is associated with no citizen risk.

Besides the citizens' access to consent, citizens are protected by a number of authorities, e.g. the Scientific Ethical Committee System and the Danish Data Protection Agency and data controllers such as the SSI.

It should be noted, however, that today the legislation makes it possible to collect and do research on health data, e.g. genetic data, without the consent of citizens or an ethics committee having performed a research ethics review. Usually, research on health data is approved only by the Danish Data Protection Agency.

Right to self-realisation

Human self-realisation is based on values and could express a diversity of values. One could argue that a person should have the possibility of deciding on the specific use of his or her tissues or data to ensure that any potential use is consistent with his or her own values and views.

The consequence is the right for individuals to refuse that their tissues or data are included in the basis of a research project.

Ownership right

Based on the belief that a person owns his or her body, it could be claimed that the person also has ownership of or at least has a strong right to dispose of his or her tissues or any information derived from these tissues.

This could justify the requirement that there should be compelling grounds to waive the person's right to dispose of his or her own tissues and information. Such right of disposal could be ensured by requesting informed consent from persons when tissues or information are used in a specific research project.

Balancing the concerns

The acknowledgement that there could be a risk involved in participating in research with health data or biobank material speaks in favour of maintaining a right to self-determination for citizens.

The right of self-determination also comes from the belief that citizens should be able to influence whether their own data or biological material can be used in research they do not find acceptable given their own set of values, or from the belief that we own our bodies.

However, there may be different opinions about how important these arguments are and how they should be balanced. As we will see later, there can moreover be conflicting concerns.

Does self-determination stand in the way of quality research?

The more comprehensive and complete the data sets and tissues directly accessible to researchers are, the more effective, precise and reliable research will be, all things being equal. Thus it must be assumed to provide more benefits all other things being equal. Seen from the perspective of Danish business, good access conditions will moreover be an advantage in international competition. So, there are several good reasons why society should want – and researchers should prefer – to promote good access conditions.

The specific informed consent is in some cases considered to obstruct research inappropriately. Experience shows that the response rate to researchers' requests for consent is often low. If those who do not respond to consent requests differ relevantly from the remaining research population, a so-called *selection bias* could occur which could potentially distort the research conclusions, or create suspicion to that effect. Studies have indicated that such suspicion could be well-founded. In other cases, evidence has shown that even in low response rates, results have proven true.

The question is then if such bias or suspicion thereof can be assumed to be so detrimental to results that it could justify restricting the citizens' right to self-determination. There is hardly any doubt that in some types of studies completeness is so important, the significance of research so great, and the risks imposed on participants so small that it would seem reasonable to loosen the current requirements for consent. On the other hand, it is hardly possible to use such justifications to argue in favour of limiting the right of consent in general.

It could also be considered if restricting the right to self-determination is the only acceptable solution to the problem: Should the fact that some citizens fail to respond

to consent requests deprive everyone of the *possibility* to give consent? An alternative solution could thus be to give everyone the possibility of giving their consent, but to include those who do not respond in research (read more about presumed consent and *opt out* below).

Can high participation rates be expected?

Researchers can to some degree themselves influence participation rates, e.g. through their contact with the research participants. Confidence in researchers or the impression that research is important can be assumed to have great impact on participation rates. In Denmark, researchers have had no reasons to doubt the population's support and trust in research.

Is it an administrative burden to obtain consent?

Obtaining informed consent also poses another problem; In an environment of increasingly complex collections of data and biological material, perhaps even across borders, and requests for even more efficient research, the burden of obtaining informed consent grows in parallel. The traditional requirement for explicit informed consent in other words makes research into large data sets slow and expensive.

But it does not necessarily have to be that way. Obtaining consent via electronic platforms would reduce administrative burdens. The authorities in Denmark already use electronic mail to communicate with their citizens. But this could involve other problems, e.g. of ensuring that research participants understand the research they are participating in.

Does the informed consent model fulfil its purpose?

It is being discussed if at all the informed consent model is fulfilling its purpose, namely to protect the self-determination of citizens/research participants. Many research participants do not consent to research because they have familiarised themselves with the research implications and can consent thereto, but rather because they trust that research is invariably conducted in an ethically responsible manner.

Therefore, researchers should be careful of seeing consent as a guarantee that the values of the research participant are respected. Every purpose for which consent can be obtained is not necessarily endorsed. Informed consent can therefore be considered as an inadequate instrument to protect the interests of research participants and to ensure continuous trust.

On the other hand, many research participants could be assumed to know that they run a small risk by participating in research. Surveys show that many people – but not all – actually find it unnecessary to consent to or understand each and every research project. Many people trust that research takes place in an ethically acceptable manner. And many people prefer that research is conducted as smoothly and efficiently as possible.

Specific, broad or meta consent

The challenges inherent in the informed consent as it is used today could be due to the fact that it originally emerged in clinical settings in the dialogue between the physician and the patient. In modern research, and especially when health data and biobank

research are involved, there is no physician-patient relationship. The relationship between citizens/research participant and researcher has other features, which could suggest that there is a need to adjust the communicative form.

Different attempts have been made to develop the informed consent. The table below gives an overview of some of the relative advantages and disadvantages attached to current consent models and two alternatives.

Irrespective of the choice of consent model, it can be a challenge to ensure that everyone responds. Therefore, a decision should be made about whether to enrol those who do not respond in research, e.g. based on the presumption that they would consent.

Presumed consent and opt out registers

Presumed consent could, however, also be an alternative to explicit consent. Today, researchers are allowed to confiscate biological material collected by the health services, even though consent to use it in research has mostly not been obtained. Any such use is subject to an ethics committee having assessed if e.g. the research could impose unreasonable burdens on research participants.

There is, however, a way of avoiding that any biological material, e.g. a blood sample taken at the hospital, be included in research because citizens have the possibility of registering in the Danish Tissue Application Register. Such *opt out* registers could be extended to other kinds of research.

Many people are even criticizing the designation of "presumed consent", which some believe can be translated into "lack of consent and mandatory participation", possibly with an option to withdraw instead. Against this background, the relevant ethical discussion of the so-called presumed consent is initially to find out when it would be acceptable *not* to seek consent and next whether there should be an *opt out* possibility instead. Others point out that there could be situations where the risk is so small and the research is described as useful and entirely uncontroversial. In such situations, "the presumed consent" with an associated possibility to *opt out* could perhaps be said to constitute a pragmatic compromise.

Resource	Research biobanks	Clinical biobanks	Biobanks in general	Biobanks in general
<p>Consent model</p> <p>Exceptions</p>	<p>Specific informed consent</p> <p>Exception; consent withdrawal</p> <p>Present model</p>	<p>Presumed consent</p> <p>Opt out</p> <p>Present model</p>	<p>Broad/general informed consent</p> <p>Possibility of consent withdrawal, presumed consent</p> <p>Alternative 1</p>	<p>Meta consent</p> <p>Possibility of consent withdrawal, presumed consent</p> <p>Alternative 2</p>
<p>Description</p>	<ul style="list-style-type: none"> • Research generally requires written informed consent with specific scope, i.e. tissues may only be used for the purposes described in the participant information sheet. • An ethics committee can exempt research from renewal of consent, e.g. if it is assessed that research participants will not be burdened thereby. • Consent can be withdrawn, however, with no effect on data already collected. 	<ul style="list-style-type: none"> • The tissues of patients can be included in research if an ethics committee can approve thereof even if consent was not initially given to allow research with the tissues. • Citizens can withdraw completely from research on clinically collected material (opt out) by registering in the Danish Tissue Application register (Vævsanvendelsesregisteret). Information about this possibility could be communicated in e.g. folders available at the relevant department. 	<ul style="list-style-type: none"> • Tissues can be used in future research projects, possibly within certain contexts such as "cancer research". • Those who do not use the possibility to give their consent may if relevant be included in research (presumed consent). 	<ul style="list-style-type: none"> • Everyone has the possibility of giving or refusing consent and has the possibility of either specific or broad consent, depending on whether they trust/can support the research. Consent could be given, e.g. when the citizen turns 18. Choices can be registered electronically. • Those who do not use the possibility to give their consent may if relevant be included in research (presumed consent).

	<p>Advantages</p> <ul style="list-style-type: none"> • In principle, research only takes place upon authorisation from the research participant based on information about the specific project. • The exemption possibility implies that self-determination only is given significance when deemed appropriate. 	<ul style="list-style-type: none"> • Research can take place without requiring the consent of patients if an ethics committee can approve of this. This way problems of for example unresponsiveness to consent requests are avoided. 	<ul style="list-style-type: none"> • Promotes self-determination in regard to the possibility of giving trust-based consent. • Research takes place upon consent, but researchers are more free to find new ways without having to obtain a renewal of consent. 	<ul style="list-style-type: none"> • Compared to today, it could improve the data basis and thus the quality of biobank research. • Promotes both self-determination for those who want to offer broad consent and for those who want to decide whether or not to participate in each specific research project. • Provides an incentive for building trust and support in research because this increases willingness to give broad consent.
	<p>Challenges</p> <ul style="list-style-type: none"> • Many people consent without having familiarised themselves with the implications of research, e.g. because they trust researchers or do not understand the participant information sheet. Support for research could thus prove weak. • Inflexible if consent must be renewed whenever research makes an unexpected turn. • Low response rates can make results prone to inaccuracies. 	<ul style="list-style-type: none"> • Missing consent combined with lack of knowledge about the possibility of withdrawing from research (opt out) is an expression that self-determination is of little significance and could make the model vulnerable to distrust. 	<ul style="list-style-type: none"> • Can hardly be described as informed consent because it is difficult to predict in which way research is going. The gap between the participant's values and the research to which his or her tissues are subject could therefore widen over time. • If subject participants choose to withdraw their consent, various forms of research are impacted. 	<ul style="list-style-type: none"> • Shares many of the disadvantages seen in specific and broad consent, e.g. concerning understanding the consequences of participation. • Enrolling those who do not take the opportunity to give their consent must be assumed to introduce some degree of uncertainty about whether research is actually supported. • Implementation is resource-demanding.

EDUCATION

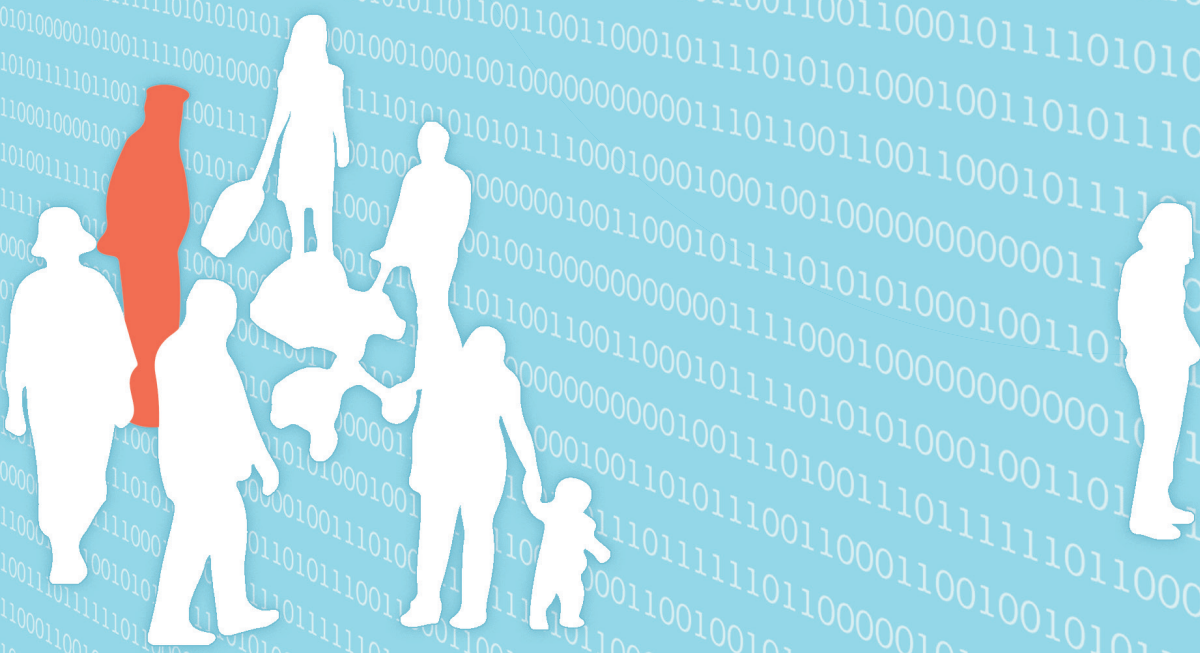
GENETIC MATERIAL

SIDE EFFECTS

BLOODSAMPLE

DIAGNOSE

MEDICINES USE



5. Recommendations

In the following, the Danish Council of Ethics presents its recommendations based on the four essential values described in the preceding sections. All members of the Council agree that the four values are important in achieving responsible handling of health data and biobanks. However, the members prioritise these values differently.

Benefit and solidarity

The Danish Council of Ethics finds it positive that citizens make their biological material (e.g. blood samples) and health data available to research as it must be assumed that research will benefit patients in the long term. Participating in research is a solidarity-based and community-serving act.

Private and public operators that dispose of or use publicly funded collections of data and biological material should be subject to requirements that support the underlying solidarity-based participation in research and an efficient exploitation of the collections. For example, it is considered good principles that

- access to such collections are accompanied by requirements that all resulting research conclusions are made publicly available.
- provided data and biological material as soon as possible are made available to other researchers, limited only by the sensitiveness of data, patenting requirements, etc.

All members of the Council find that it should not be possible to trade biological material and health data stored and processed under public management, but that it should be available for research purposes etc. One member (Mickey Gjerris), however, finds that if private operators through their use of any of these collections generate a profit for themselves, it should be ensured that such profit will also benefit society. If this can best be secured through direct payment of data usage, such arrangement is preferred.

Some members (Gorm Greisen, Thomas Ploug, Christian Borrisholt Steen, Kirsten Halsnæs, Lise Von Seelen, Jørgen Carlsen, Jacob Birkler, Poul Jaszczak, Karen Stæhr, Signe Wenneberg, Lillian Bondo, Lene Kattrup) find that it should neither be possible to trade collections stored and processed under private management. If data and biological material attain commercial value, it could have a number of inappropriate consequences. If it becomes generally known that it is possible to earn money from giving data and biological material, then it might change support for the present solidarity-based giving of data and biological material in Danish research and in the health sector.

None of the Council members oppose the commercial development of new products, etc. on the basis of research in health data and biological material.

Privacy

Security breaches and vulnerabilities are a growing societal problem, which within health research could have serious consequences for citizens, research and healthcare services. Admittedly, in the research context, there are only very few examples of security breaches that have caused harm to citizens. However, a number of scandals outside and close to the research environment do serve as a reminder that times are changing in response to these days' powerful advances in bio and information technology. The number of security breaches have increased significantly overall.

Ensuring better protection of citizens' privacy could prove arduous, slow down research and necessitate significant investments. The Danish Council of Ethics nonetheless finds that it is necessary to meet the concerns of both citizens and research (as described in sections II and III above). There is a need to put more focus on the culture of handling health data and biological material, just as there is a need to tighten the requirements imposed on authorities and researchers in their handling thereof.

A. Focus on the culture surrounding health data and biological material

- Security involving the use of health data and biological material should be enhanced through focus on formal managerial responsibility and learning because many security breaches seem to emerge from errors and lack of knowledge, etc. Managerial responsibility should apply to all layers of management in the institutions engaged in health data or biological material research, from top-management to divisional level.
- Generally, the research environments should work with accountability in research.
- In order to promote harmonised practices, best-practice standards for the protection of privacy in the area of health data should be defined, e.g. based on Statistics Denmark's privacy policy.

B. Tightened requirements for the handling of data and biological material

The protection of citizens' privacy should generally be upgraded. The risk of data leakage is not least related to the volumes of health data and biological material being collected, how much these are processed and exchanged, and how many have access to them. The following conditions should apply:

- Det bør indskærpes, at kun den nødvendige personkreds bør have adgang til It should be emphasised that only the required group of persons should have access to biobank material or health data at individual level, regardless of whether they are anonymised or pseudonymised. Compared to the current practice, it should generally be considered if the group of persons with access to registers of health data and biological material can be narrowed.
- Any application for distribution of sensitive personal data or biological material for research purposes should include considerations about privacy risk in the specific case. Privacy risk is greater when for example small or vulnerable groups are being

studied or in research involving particularly sensitive information (see section II about "particularly sensitive information"). The definition of particularly sensitive information changes with the technological development and should therefore be assessed regularly.

- The authorities' approval of research projects that involve more than a minimal privacy risk for citizens should to a higher degree be in the form of a specific research ethics review, i.e. to the extent possible an independent review and balancing of diverse concerns involved, conducted by a group of appropriate composition. Although the legislation already acknowledges that the distribution of data involves a line of conflicting concerns, practice shows that it is often left for researchers and data controllers to assess the justifications for distributing and processing data. At the same time, the advances within biotechnology and information technology imply that citizens have increasingly more at stake (see section II).
- In studies involving a high privacy risk, any processing should ideally be centralised at the data controller, implying that the processing of data takes place "within the walls" so to speak, cf. the practices of Statistics Denmark. While this practice reduces to a minimum the number of people with access to the data and thus the risk of data leakage, it also enables valuable research into sensitive data in a qualified manner.
- The Act on Processing of Personal Data's equalising of anonymisation and deletion should be abandoned given the improved possibilities of re-identifying citizens based on very few data or biological material. Every biological sample contains large volumes of personally identifiable data that are so relatively easy to read that any removal of traditional identifiers such as name and civil registration number can no longer be seen as de-identification on a par with deletion.
- Compliance with the Act on Processing of Personal Data should be promoted through more systematic supervisory control.
- Security breaches in health research should to a higher degree be systematically registered at institutional level and made publicly available. Today, data breaches in research are registered only to a limited extent, which makes it difficult to track the development. By making the information publicly available, the basis is established for society to discuss the advantages and disadvantages of researchers' access to health data and biological material. It should be noted though that the aim should not be to single out individual researchers who perhaps by mistake have breached the data processing rules.
- Any unlawful data registers and biobanks should be cleared out. The DAMD case highlighted illegitimate collection of data for the clinical quality databases. It is unfortunate if such cases should foster uncertainty about whether the collection of data and biological material takes place within the rules of the law. Considering that the Danish Data Protection Agency has had limited means to exercise adequate supervision, it could be considered on a case-by-case basis to introduce an "amnesty" system.
- Law infringements, especially where deliberate and resulting in security breaches, should be linked to reinforced penalties. To illustrate, institutions could lose their access to data/biobanks for a defined period of time, which today is practised by Statistics Denmark.

Trust

Preserving citizens' trust in research and the health sector requires an investment of efforts like it does to protect citizens' privacy – the more important we consider the trust of citizens to be, the more we should invest into preserving that trust. The Danish Council of Ethics finds that citizens' trust should be given high priority in particular for the benefit of research itself, including the favourable conditions that exist for Danish register research (see section III). Evidence shows that there is a connection between trust and e.g. self-determination and privacy. The Council moreover finds that importance should be attached to enhancing transparency in health research compared to today's practice:

- When health data and biological material are collected or used, there should be public access to information about the purposes of research projects and the access to data, including information about the roles and obligations of private operators.
- Every citizen should have access to information about what kind of research is applied to their data or tissues and who have requested access thereto, as well as about the possibilities of withdrawing from research.
- Every citizen should have access to checking the correctness of data collected about them and information about how to correct erroneous information.
- There should be access to information that could raise overall awareness about which data and biological samples are being collected and to what kind of research these are currently applied.

If the volume of information is massive, solutions should be developed to ensure the information is as comprehensible as possible.

Self-determination

For the background to the recommendations below, reference is made to the consent models on page 34-35.

The members of the Danish Council of Ethics agree that the informed consent per se does not adequately protect research as well as citizens. But the Council is divided on what the consequences thereof should be. Some of the Council members find that the citizens' self-determination should be reinforced (Position A below). By contrast, other members find that reinforced self-determination will neither serve citizens nor research in the best way (Position B below).

A. Citizens' self-determination should be reinforced by giving them more options (meta consent – see comparison with other consent models in the table on page 34-35)

Some Council members (Thomas Ploug, Lene Kattrup, Lise Von Seelen, Christopher Arzrouni, Christian Borrisholt Steen, Poul Jaszczak, Mickey Gjerris, Steen Valentin, Signild Vallgård, Jørgen Carlsen, Christina Wilson, Signe Wenneberg) find that every citizen should have the possibility of, in some form or other, giving their informed consent to research on biological material and particularly sensitive health data. The members assess that researchers have no reason to doubt the Danes' trust in and support for research and thus no reason to fear lack of participation.

The members find that the present model for obtaining consent in research should be

reviewed and recommend to introduce a so-called meta consent, implying that citizens will be given the possibility to decide themselves when they want to give or refuse consent in regard to their health data and tissues. More specifically it is recommended:

- that citizens be given the possibility to decide themselves when they can give broad consent, and when they wish to give specific consent to individual research projects.
- that citizens can indicate their consent wishes within a number of main areas such as data held in records, register data and biological material.
- that citizens at any time can change their consent wishes, including withdraw their consent.

Obtained consents should be registered electronically via existing platforms such as sundhed.dk or e-boks, so that in many cases the need for renewal of consent will be limited.

Some of the mentioned Council members (Thomas Ploug, Lene Kattrup, Steen Valentin, Jørgen Carlsen, Signe Wenneberg) find that citizens who do not take the opportunity to state their consent wishes can be included in research (presumed consent) provided the research is not deemed by an ethics committee to burden citizens significantly.

However, the members do not find that reinforced consent as described will reduce the need for strengthening other precautionary measures, for example with regard to regulatory control.

B. Other forms of protection should have the highest priority

Some Council members (Jacob Birkler, Gorm Greisen, Kirsten Halsnæs, Karen Stæhr, Lillian Bondo) find that other precautionary measures should be given higher priority. The informed consent does not adequately protect the interests of citizens, e.g. because many citizens are not interested in knowing or have difficulty understanding what it entails to participate in research. Research should therefore first and foremost take place in a relationship of trust between citizens and researchers who show accountability with respect to trust. The members recommend

- that the current practice of using informed consent be maintained.
- that the Danes' trust in research be based on the premise that research is made subject to adequate data legal control and research ethics review, including the need for obtaining renewed informed consent, and with up-to-date data security.

C. Joint recommendations regarding self-determination

- Research with *particularly sensitive data* (see section II) should on the legislative front be equalised with research with biobanks with respect to requirements for regulatory review and self-determination.
- The use of informed consent or exemption from consent should be accompanied by the possibility of withdrawing from research, cf. the Tissue Application Register. The Danish citizens' knowledge and understanding of presumed consent and the possibility of withdrawing entirely from research should be investigated and promoted.

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The Danish Council of Ethics offers advice and generates debate on biotechnology which affects people's lives, the countryside, the environment and food. In addition the Council is engaged in ethical questions otherwise connected with the Danish health service. The Council consists of 17 members appointed by Danish Parliament and relevant ministries. Read more about the Danish Council of Ethics at www.etiskraad.dk