Tussen privacy en wetenschapsvrijheid. Regulering van gegevensverwerking voor medisch-wetenschappelijk onderzoek
Ploem, M.C.

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: http://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.
SUMMARY

Introduction (chapter 1)
In our society, academic freedom as well as privacy are considered fundamental values. When using medical data for health research, these values can come into conflict. According to researchers, due to data protection legislation medical data are not sufficiently available for research. From a privacy perspective, it is claimed that citizens need adequate protection of their privacy interests when such data are being used. With insufficient privacy protection, the risk exists that citizens do not feel free to seek medical assistance or to provide information that is relevant for their medical treatment. This study concerns the – sometimes restrained – relationship between medical research and privacy protection.

The objective is to give a systematic overview of privacy regulations regarding (medical) research, to identify and analyse the problems experienced by researchers as a result of data protection legislation, and to suggest amendments to present law. The central question is the extent to which national (and international) legal standards provide for a well-balanced regulation of data processing for medical research and whether these standards are also appropriate in other respects. The following sub questions can be distinguished:

- Which human rights are at stake, what is their significance, and which frame of reference can be derived from that for the legislator?
- Which privacy standards apply to research and statistics and to medical research respectively, and how have these standards developed? What are the status and the scope of these standards? Do they express a balance between research interests on the one hand, and privacy interests on the other? Have these interests been weighed in a different way as far as medical research is concerned as compared to research in general?
- Which problematic issues arise if the present law is applied to the practice of scientific research and to the subsequent phases of medical research in particular? How could the law be shaped to meet these problems, taking into account the human rights aspects?
- Does the existing law need amendments and/or additions against this background? If so, on which points? Which forms of regulation are most appropriate with regard to the different issues?

The human rights framework (Chapter 2)
Privacy interests are in particular protected by the right to privacy or private life, also embedded in the Dutch Constitution. According to this right, everyone is entitled to (inter alia) protection of his or her informational privacy. It goes without saying that this also holds for medical personal data which are sensitive by their very nature. However, the right to privacy is not absolute: one should always take into account that it can come into conflict with other freedoms or with the general interest. If the processing of personal medical data (by the public authorities) interferes with the right to privacy, several conditions should be fulfilled, for instance that an act of parliament provides for this and that the requirements of necessity, subsidiarity and proportionality have been met. Furthermore, international treaty law and the Dutch Constitution oblige the legislator to elaborate safeguards with regard to the recording and
circulation of personal data. In this respect, usually no distinction is being made between so called vertical and horizontal relationships.

The interest of free research is protected by the freedom of science, the right to freedom of expression and (in the field of health) the right to health care. The positive obligations of the State resulting from these basic rights include in particular the duty to guarantee sufficient room to collect and exchange information for scientific purposes. At present, however, these obligations do not (yet) entail a legal duty to see to it that researchers receive the (personal) data they need. It is in particular in its classic dimension that the freedom of science (and the freedom of expression closely linked to it) has a direct legal significance for the collection and processing of personal data for research and statistics. The limitation of or the interference with this freedom, more in particular the freedom of data collection and processing, needs an unambiguous legitimation: it should remain as limited as possible, it should not be disproportional in relation to the objective pursued with the interference, and finally it should take place for a legitimate interest. Protection of private life is such an interest, at least potentially. Finally it should be noted that the freedom of science applies only as a fundamental freedom if the data processing concerned can rightly be looked upon as part of scientific activity, i.e. that its purpose is to contribute to the general interest by enlarging scientific knowledge (which is to be distinguished from market research or direct marketing, for instance).

As indicated above, individual privacy interests and the general interests connected with medical research can come into conflict. That holds also for the human rights underlying these interests. If, in such a situation, one takes the right to privacy as a starting point, then the conditions that have to be fulfilled in case of interference with the right to privacy (ex Article 8 European Convention of Human Rights) constitute the limit within which a potential restriction of this rights for the cause of science has to take place. In this context one can make a distinction between conditions that relate to forms of regulation, the quality aspects involved, and procedural safeguards on the one hand, and factors linked to the requirements of necessity (also called ‘balancing factors’) on the other.

Privacy standards for research and statistics in general (Chapter 3)
A review of international and national privacy standards in the field of research and statistics shows that these take scientific activities into account, in particular in that the phase of data collection is facilitated. This flexibility mainly concerns the so called secondary data collection, i.e. the re-use of already stored data for scientific and statistical purposes. Besides, there are also some standards that facilitate the further processing of data.

There have not been major shifts in the weighing of privacy against academic interests: over time, the room left by privacy standards for research has basically remained the same. For instance, both at the national and at the international level the rule has always been that the individual has no unconditional or unlimited claim to protection of his personal data. At the same time, the interests of science have never prevailed to the extent that a legal duty to provide personal data has been enacted. On the other hand, in the course of time some shifts of emphasis have taken place, such as a certain increase in standards that facilitate research. This was mainly the result of the entering into force (and implementation into national law) of the EC Privacy Directive of 1995, of which several provisions take into account the practice of research and statistics.
Summary

Privacy standards for medical-scientific research (Chapter 4)
The national and international privacy standards do not only take into account research and statistics in general; also the needs of medical scientific research are explicitly addressed in the law. In particular, the accessibility of medical data is enhanced (see Article 7:458 Dutch Civil Code, as well as the – non binding – Principle 12.2c of Recommendation R (97)5 of the Council of Europe). With regard to further data processing mention should be made in particular of the exception to the rights of data subjects laid down in Principle 8.2d of Recommendation R (97)5.

A comparison of the standards reviewed in Chapter 3 (research in general) and Chapter 4 (medical research) demonstrates that for medical research, at least on certain points, specific standards have been developed that usually provide extra protection to data subjects. To justify these specific standards, reference is made to the special or sensitive nature of medical data and to the fact that when medical data are being processed most often a professional duty of secrecy applies. Scientific researchers and others such as health professionals and health care institutions who conduct research in this field have to reckon with (inter alia) a strict consent regime, the need to provide at least an opting out option and far-reaching obligations concerning data security.

Privacy protection and medical research in practice (Chapter 5)
On the whole, the present law is not ill-balanced, in the sense that it disproportionally hampers data processing (collection, storage, use et cetera) for medical research, or that it insufficiently protects the data subjects in their privacy interests. Nevertheless, with regard to specific parts of the law, substantial obstacles to research exist, but also deficiencies in privacy protection. Furthermore, certain quality aspects of the law in force (clarity, consistency, recognizability) excite comment.

As far as the collection of data directly from individuals (primary data collection) is concerned, the main obstacle is to obtain the address information needed to approach them personally. Until recently the law was flawed on this point: it did not provide guidance for access to address files in the population register, so that every municipality could adopt its own policy. Since 2001 rules have been enacted (Article 67 Decree on the Municipal Population Register) that aim at removing the obstacles reported by researchers. However, as long as the (exact way of) involvement of data subjects has not been elaborated in the Decree (or the Act on the Municipal Population Register), it remains to be seen whether the problems belong indeed to the past.

As to secondary data collection, a first obstacle for research are the rules on preservation of patient data for research purposes. The rules concerned would be more in balance if – similar to provision of patient data for research – they would offer (at least on certain conditions) a more flexible regime for patient involvement. The present rule is that identifiable medical data can only be preserved for research when the patient has explicitly agreed thereto. Whereas there should be more room for research with regard to longer preservation, on the contrary, when health professionals use patient data that are already at their disposal due to their involvement with the patient's treatment, the privacy interests of data subjects deserve more protection. That kind of research (i.e. by health professionals themselves) is not regulated at all, while in this situation privacy interests of data subjects can be at stake just as well.

There are no strong indications that the present rules in the Medical Contract Act on the provision of data to external researchers seriously hamper research activities. This does not alter the fact that the application of those rules in practice can give rise to
Summary

problems and bottlenecks. If the consent of data subjects has to be obtained, there is the risk that one cannot meet all the requirements (such as voluntariness) that apply in this context. When the exceptions laid down in Article 7:458 Civil Code are invoked, in particular the concept of data coding and the legal status of coded data may raise questions.

When data are collected from other registers, in particular the accessibility of the register of mortality causes, held by the Central Bureau of Statistics, causes problems. The question is whether the recent change of the law (insertion of a new Article 42a in the Act on the Central Bureau of Statistics) is a sufficient solution to this problem. Overall it seems to be sensible to provide (when further elaborating Article 42a) that a refusal of the Central Bureau to procure data must be motivated by it, allowing researchers to oppose and to appeal against such a decision.

If the present law is not always well-balanced with regard to data collection for research purposes, this is less of an issue in the further stages of data processing. This does not alter the fact that the obligations of researchers in this phase (concerning data security, quality of data, notification, publication in non-identifiable form) raise question-marks, for instance what adequate protection of medical data bases requires, how long and in what form data may be preserved et cetera.

An important problem not caused by privacy legislation but by other factors (for instance the high cost of data protection) is the aloofness of researchers to put the data collected by them at the disposal of other researchers. The use of data for research purposes should not simply end with eliminating the data but – where this is sensible – with preserving (and archiving) them (‘data sharing’); this of course within the limits of the privacy legislation in force.

Passing of medical data for research purposes from the Netherlands to Member-States of the European Union and vice versa should, in principle, be free of constraints. However, it is not to be excluded that specific obligations resulting form the principle of medical secrecy may hamper such a data exchange. Further elaboration of general privacy standards in the form of a European Code of Conduct seems useful on this point.

Passing of medical data from the Netherlands to a research center outside the EU is in principle only allowed if the country concerned offers an appropriate level of protection. If that is not the case, passing of data is still possible on the basis of (inter alia) an authorization of the Minister of Justice. The burden for researchers of obtaining such a permit should not be underestimated, however. The development of (model) contracts that satisfy the requirements made by the European Commission for this purpose and that do justice to the particular aspects of research with medical data, could facilitate the international exchange of data to a considerable extent. In this context also European self regulation can play a useful role.

Appropriate standards for medical-scientific data research (Chapter 6)

In connection with privacy law one can make a distinction between substantive rules, rights of data subjects (including so called ‘rights to have a say’, such as a right to consent or objection), and rules that provide for systematic supervision on compliance with the law by an independent agency. These three categories of rules should form part of a legal regime for medical data research. It must be noted that such a regime should not rely too much on the rights of data subjects because in an era increasingly dominated by information technology those rights will in practice not always provide the protection envisaged. Furthermore, substantive rules and rules relating to super-
vision should play a more significant role to the extent that the data subject has less of a say, in particular when he has no right to consent but (only) to oppose.

**Substantive rules**

From the necessity requirement (see Chapter 2) one can derive a number of substantive rules. Of foremost importance is the principle that as far as possible anonymous or (if that is not feasible) coded data should be collected and processed. When coded data are collected no identifiable data are provided to researchers but only a key to enable them to connect research data to the individuals concerned. In this way not all possibilities (such as supplying research records with fresh data or approaching data subjects with a questionnaire in a later phase) are excluded, whereas at the same time the risks of illegal or inappropriate use of data are substantially reduced. In my opinion coded data are (in principle) identifiable data (in the sense of the Data Protection Act), but because of the privacy protecting effect of coding an appropriate (i.e. less stringent) regime for the use of such data is justified. This holds in particular for the rights of data subjects (consent or objection, information and other rights), but also some of the substantive rules, such as the obligations relating to data security, can be less strict in case of coding.

**Rights of data subjects**

Among the most important rights of data subjects is the right to have a say over the use of their medical data for research including a right to be informed about that use. As indicated above, the further elaboration of these rights is connected first of all to the form in which these data are being processed. If they are encoded (and therefore not directly identifiable) offering data subjects the possibility to object is in principle sufficient. Nevertheless, there may be situations, for instance research with genetic data, in which in spite of encoding a stricter application of the rights of data subjects may be warranted. Collecting and using directly identifiable data supposes a consent system with an individual right to consent.

**Supervision and enforcement**

Supervision and enforcement should not only take place by means of a supervisory agency (Data Protection Authority) backed by the courts, but also by means of review of data research by an independent body such as an ethics review committee. These committees would seem pre-eminently suited for that purpose, taking into account their expertise in reviewing medical research protocols.

**Conclusions and recommendations (Chapter 7)**

The conclusion of this study is that the existing legislation (Medical Contract Act, Data Protection Act, Act on the Central Bureau of Statistics, and the Act/Decree on Municipal Population Registers), and self regulation (Code of Conduct for Health Research) need to be modified in several ways, on the basis of the following considerations:

- **Unclear legal status of encoded data**
  
  To remove (or to prevent) the present legal uncertainty unambiguous rules are needed at international and national level.

- **A too predominant role of the consent requirement**
  
  The emphasis within the present law is too much on consent. Standards relating to collection and processing of medical data for research are to be developed primarily from another point of view: on the basis of the principle of subsidiarity that is more fundamental in privacy law. Against this background, the law should first of all aim
Summary

at keeping the interference with private life as limited as possible. This will also help to meet the problems connected with asking explicit consent that exist in practice. Another point is that the consent of the data subject fully legitimates the provision (or collection) of data. The present safeguards that apply in case of departure form the consent requirement (the research is in the general interest et cetera) should apply to any collection and processing of data for medical research irrespective of whether or not consent is being asked.

- Too strict rules for collection and processing of coded data
The present law has been structured in such a way that explicit consent is in principle required, not only when directly identifiable data, but also when coded data are being collected. The fact that coding reduces the interference with privacy justifies a less stringent regime of protection (see chapter 6). Taking this into account, while for provision of directly identifiable data consent should be required, when coded data are passed to researchers (so that they can not identify the patients concerned), the possibility to object would be sufficient. Also on other points, a more flexible regime is proposed for coded data, for instance with regard to the duty of notification and the rights of data subjects.

- Too few transparency safeguards
The present law offers insufficient safeguards for the transparency of data collection and processing for medical research. Laying down an explicit right to information in Article 458 of the Medical Contract Act and appointment of a privacy functionary for the sector of medical research can be important ways to better safeguard transparency.

- The lack of systematic supervision of compliance with the law
The existing legislation does not provide for systematic supervision on application of and compliance with the rules by an independent body. Although the provisions of the Data Protection Act play an important role in this respect, additionally the Medical Contract Act should provide for structural review of collection and processing of data research by an ethics review committee.

- Standards only on 'provision of data to researchers' are insufficient
Finally it should be noted that at least the main rule in the Medical Contract Act only addresses the provision of medical data to researchers, whereas preservation of data and their use by health care providers themselves should be subject to similar principles. This can be achieved by applying one and the same legal regime both to provision of data and to other forms of data processing for medical research. Another advantage of that approach is that quality aspects (such as the transparency, uniformity, recognisability et cetera of the rules concerning the processing of medical data for research purposes) are furthered by it.

Finally the study recommends to develop a European Code of Conduct relating to medical scientific research.