



## **CODE OF CONDUCT FOR MEDICAL RESEARCH**

The Council of the Federation of Medical Scientific Societies, whereas:

- health research forms an integral part of health care and considering also the importance of health research for patient care and public health in general;
- within the field of health research, considerable importance has long been attached to the protection of the individual privacy of those whose data are used in an investigation;
- in the course of a health research project, the protection of the personal privacy of those whose data are or can be used in a health research project on the one hand must be weighed against the health of (future) patients/consumers and general public health interests, on the other;
- it is advisable, due to the Law for Protection of Personal Data and the Law for the Agreement on Medical Treatment, to formulate rules of conduct in a Code for the use of medical data for health research;
- the aim of this Code of Conduct is to provide support in the judgement of the above-mentioned balance of interests;
- this Code of Conduct is drawn up after satisfactory consultation with key figures of the organizations of the parties concerned;

has established after consultation with the member societies the following rules of conduct.

## 1. Definition of terms

In this Code of Conduct the following definitions apply:

- a. *Health research*: medical scientific research (such as patient-oriented investigations, epidemiological or health care research) whereby use is made of previously available data or data collected for that purpose, for which professional confidentiality is applicable under Article 88 of the Individual Health Care Professionals Act.  
Medical research in the sense of this Code of Conduct does not include: scientific research as defined by the Law for Medical Scientific Research with Humans (WMO) and described in article 1 under b of that law;
- b. *the investigation*: a specific investigation as defined under a which is described in a research protocol;
- c. *the research protocol*: the description of the design of and plan for the execution of a specific investigation;
- d. *researcher*: the person or persons who are named in the research protocol as the one or ones responsible for execution of the investigation;
- e. *care provider*: the person who cares for a patient in the sense of the Act on the Medical Treatment Contract;
- f. *controller*: the natural person, legal body or any other who (or the Board which), alone or together with others, determines the goal and the means of processing patient data and within whose organization the researcher works. As a rule, the one responsible in the sense of this Code is considered to be the head of the research group or the research institute or a similar type of unit to whom the researcher must justify his decisions according to the hierarchy;
- g. *processor*: the person who processes the data for the responsible researcher without being subject to that person's direct authority;
- h. *data subject*: the person the data pertains to;
- i. *supplier*: the person who supplies the researcher the data needed for the investigation;
- j. *data*: everything which relates to a data subject and can be used for a health research project;

- k. *anonymous data*: data which can only lead to identification of the natural person after application of unreasonable means or disproportionate time and effort;
- l. *personal data*: every fact about an identified or identifiable natural person;
- m. *directly identifying personal data*: data with which the researcher can directly or in combination with one or more communication data establish the identity of the involved person;
- n. *indirectly identifying personal data*: data which, although they do not lead directly to the identity of the involved person, nevertheless make it possible for the researcher, by using the means available to him, to determine the identity of the involved person without spending a disproportionate amount of time and effort;
- o. *communication data*: data, such as last name, first name, initials, title, sex, date of birth, address, postal code, city, and telephone number, and other data needed for communication as well as the bank and postbank account numbers of the involved person;
- p. *coded data*: data which do not include directly identifying personal data and which have been encoded such that the identity of the involved person can only be determined by the intervention of the supplier or an independent third party and after application of the key to the code;
- q. *database*: every structured batch of data that is accessible according to specific criteria;
- r. *medical-ethical review committee*: a review committee that has been established partly to evaluate this type of investigation and which is sufficiently qualified for this purpose.

## **2. GENERAL CONSIDERATIONS**

### 2.1 Tasks of the controller

- a. The controller ensures that the researcher adheres to the regulations of this Code of Conduct;
- b. The controller takes the appropriate technical and organizational measures needed to safeguard the personal data against loss or any form of illegal processing;
- c. In particular, the controller ensures that proper technical and organizational measures are taken such that the researchers do not have access to data within the organization of the controller other than that determined by the regulations of this Code of Conduct;
- d. Should the controller let personal data be processed by a processor, then he will also ensure that the processor takes sufficient technical and organizational safety measures with respect to the activities to be carried out. The controller oversees adherence to these measures.

2.2 Researchers carry out their research in accordance with the Law for the Protection of Personal Data (WBP), the Law for Agreement on Medical Treatment (WGBO), and the manner in which these regulations are incorporated in the present Code of Conduct.

2.3 Researchers use only those data that are necessary for the goal of the research project and that were obtained legally. The researcher exercises due care in the collection, storage and use of the data and takes all measures necessary to safeguard the data sufficiently against loss, damage, unauthorized perusal, changes, conversion or distribution.

2.4 Researchers will take care to use that type of data that offers the best possible protection of the personal privacy of the data subject. Thus whenever possible use must be made of anonymous data and directly identifying data as little as possible. of Whenever possible is also understood to mean as long as it is justifiable, in view of the nature and the aim of the investigation and the correct execution of the project.

2.5 Researchers oversee the strict adherence to this Code of Conduct by those whose cooperation they need for the research project. Personal

data are only processed by the researchers or by those who fall directly under their authority. All are subject to the pledge of confidentiality.

2.6 The researcher draws up a research protocol for the research project.

This protocol includes at least the following items:

- a. the names or name of the responsible researchers or researcher;
- b. the aim, question, methods and duration of the research project;
- c. the category of persons whose data are to be used for the research project;
- d. in the event anonymous data is not used- the reasons why another type of data is needed;
- e. insofar as not named under a- the names of those authorized to see the personal data;
- f. a description of the provisions for the protection of the data, both at the level of the controller (taking the regulations in 2.1 under b into account) as well as specifically for this research project;
- g. a description of the manner in which the researcher will satisfy the regulations of this Code of Conduct;
- h. the manner in which the results of the investigation are to be published;
- i. if directly identifying data are used, whether those involved have access to the results of the investigation and if so, how.

If desired, the research protocol is available for perusal by the data subjects and the supervisory bodies. It can be changed in minor respects in the course of the investigation. Every change must be recorded.

2.7 The researcher satisfies himself that the care provider who is responsible for the provision of the data, in general has provided the client/patient with at least a written informative pamphlet containing the following information:

- that the care provider in addition to treatment of patients and safeguarding the quality of care, also has related goals, such as the execution of health research;
- that due to the importance of these goals, data of patients can be used for these goals;

- that the care providers and the organization for which he/she works will only supply data to researchers who have declared that they will adhere to the Code of Conduct;
- that it is possible to object to the use of data for research;
- that via the care provider involved in the treatment or at a place in the institution to be indicated specifically in the pamphlet, information can be obtained about making such an objection and a record can be made of said objection;
- that the data subjects will in principle be asked to consent if personal data for research purposes are to be processed by someone other than the care provider involved in the treatment;
- that the institution has a medical-ethical review committee and a complaints committee which supervise, each in the field in which they are qualified, the interests of the patients and whose regulations if desired are available for perusal or that the care provider has joined such committees for which the same applies.

- 2.8 Data obtained for use in research may only and exclusively be used for research.
- 2.9 Data may be stored for a longer period than necessary for the relevant investigation. This storage and every eventual renewed use occur however in agreement with the regulations of this Code of Conduct, in particular article 5.5 and chapter 7.
- 2.10 If a researcher wants to supply data to another researcher, then the first researcher must be considered a supplier. The relevant regulations in this Code apply likewise to such a transfer of data.
- 2.11 A care provider who wants to carry out an investigation himself may for this purpose use the data in his possession insofar as this takes place in accordance with the regulations given in this paragraph and the data subjects did not object to the use of their data for health research.
- 2.12 Irrespective of other regulations elsewhere, the researcher is obligated to submit a proposed investigation, which he knows or presumes can lead to questions from the point of view of privacy, to a medical-ethical review committee for evaluation. In such a case the investigation may not be

initiated until this committee has given a positive recommendation. An investigation in which personal data are to be processed must always be submitted to the medical-ethical review committee.

- a. The processing of personal data for a research project must be reported to the College bescherming persoonsgegevens (the Data Protection Authority) , unless the researcher is affiliated with an organization for scientific research and:only indirectly identifying data are involved;
- b. the personal data are not coded and are only to be processed for the relevant investigation.

Or, if the personal data are directly identifying:

- a. a differentiation is made between the communication data and the research data, as described in article 7.1;
- b. the communication data with the exception of sex, house address and date of birth are not to be stored for more than 6 months after they have been obtained from the data subject and also are not coded; and
- c. the data are used exclusively for the relevant investigation.

### **3. The use of anonymous data**

- 3.1 Anonymous data can be used for health research;
- 3.2 The researcher may not carry out any procedures with the database of anonymous data (coupling, comparison, processing) with which the researcher could derive the identity of the involved individuals;
- 3.3 Anonymous data may be saved for as long as it can reasonably be expected that they can be used for health research.

#### **4. The use of personal data: the main rule**

4.1 Unless one of the exceptions of chapters 5 and 6 applies personal data may only be processed for an investigation if the data subject has given explicit consent.

For this purpose, the data subjects must be informed as completely as possible about the proposed use. The information must be understandable for the data subject and should include at least the following:

- that the supplier will contribute to the proposed investigation by supplying the data needed for that purpose;
- why the personal data of the data subject are needed for the investigation;
- the goal of the investigation, the importance of the investigation, the eventual consequences for the involved person and other aspects which the one involved in all fairness needs to know for the formation of his opinion;
- that the researcher follows a research protocol – or a summary thereof – which is available for perusal;
- that the research protocol received a positive evaluation from the medical-ethical review committee.

Once consent has been given it can always be revoked by the data subject. Insofar as possible his data are then removed from the research database. If this is not possible they are at least rendered anonymous.

4.2 For minors and the incompetent, consent is given according to the rules for proxy consent as formulated in the WGBO.

If the data pertains to a child whose parents gave their consent sometime in the past, this person can himself withdraw his consent when he turns 16 years old.

4.3 If the data are obtained from a supplier, the researcher must be sure that the supplier satisfied the regulations set down in articles 4.1 and 4.2.

4.4 A researcher may not carry out specific procedures with a database of personal data that causes more information about the involved patients to become available than that for which they have given consent. If the

database contains only indirectly identifying personal data, no procedures may be carried out with this database (coupling, comparison, processing) with which the researcher can derive the identity of those involved.

- 4.5 An investigation in which personal data are to be processed must first receive a positive recommendation from a medical-ethical review committee.

**5. The first exception: use of, coded or not coded, indirectly identifying data without consent of the data subjects**

- 5.1 If the request for consent cannot in all fairness be required, for example because this would cost a disproportionate amount of effort, data which must be considered personal data due to the recorded indirect indicators can under certain conditions be used for an investigation without consent. These personal data can be coded or not coded. The conditions are:

- The investigation must serve general (public health) interests. This is the case at any rate when the investigation is carried out by an institution for scientific research or statistics and the aim of the investigation is a publication.
- The investigation cannot be carried out without the supply of data in this form:
  - The data subject has not objected to this use;
  - Identification of the data subject is prevented within reason, as further defined in the following sections of this chapter.

- 5.2 The researcher who wants to obtain these personal data from one or more suppliers draws up a written agreement with each supplier:

- that the supplier will remove all directly identifying characteristics before supplying the data requested and, insofar as applicable, will encode it, all in such a way that the researcher cannot within reason use the data obtained to identify individuals and thus that identification is prevented within reason
- that the supplier will carefully safeguard the key to the coded data;

- that the researcher will not carry out procedures (coupling, comparison, processing) with the coded data in order to discover the identity of the involved persons;
- that this Code of Conduct in its totality will be observed by all who are involved in the investigation.

5.3 The researcher who wishes to obtain supplementary information in the course of the investigation about the individuals whose coded data have been used, asks the supplier to provide the relevant data, again in such a manner that the researcher cannot use the supplementary data to discover the identity of the data subjects and that recognition can within reason be avoided. The other stipulations of these paragraphs apply correspondingly.

5.4 The researcher will not process the data referred to in this chapter in such manner that he can discover the identity of the data subjects.

5.5 Personal data obtained according to the regulations of this chapter may only be saved insofar as it is reasonable to expect that they may be needed later for the investigation.

## **6. The second exception: use of personal data without consent of the data subject**

6.1 In contrast to that stated in chapter 4, personal data can be processed without the consent of the data subject if the request for consent is within all reason not possible because one of the following situations occurs and the other stipulations set down in this chapter are met:

- a. the request for consent can represent such a heavy burden for the data subject that the possibility of mental stress must be considered (in view of the nature or severity of the condition and eventual other situations, such as a long period between the treatment and the request for consent);
- b. the data subject has passed away or the address cannot be found or the data subject has not reacted to at least two written letters;
- c. the aim is the development of the correct random sample and the question of consent would have to be posed to a much larger number

of people than is considered necessary for the answers to the research questions because only a small percentage of them will be included in the investigation.

- d. the question of consent is not considered meaningful because the investigation is still in the first preparatory phase.

6.2 In order make use of the exception to the principle of consent under the conditions described in 6.1, the following requirements must be satisfied:

- a. the investigation must serve the general (public health) interests. This applies in any case when the investigation is carried out by an institution for scientific research or statistics and the aim of the investigation is a publication.
- b. the protocol for the investigation indicates that the investigation is worthwhile and well-founded according to scientific criteria, that it cannot be carried out without the requested data and also that it cannot be carried out in a manner that would be less of an intrusion into the personal privacy of the data subject, such as with anonymous data. If personal data must be used, they should be indirectly identifying data insofar as possible; directly identifying data can only be considered when there is no other course. This aspect of the proposed investigation should receive explicit attention in the course of the review as described in article 4.4;
- c. the data subjects have not expressed an objection to this use;
- d. other guarantees are given that the privacy of the data subjects will not be unreasonably undermined.

6.3 For the situation described in 6.1 under c, the following additional requirements also apply:

- a. this procedure is described beforehand in the research protocol;
- b. access takes place with and under the authority of the care provider involved in the treatment;
- c. access to more data than needed for the establishment of the random sample will not be granted;
- d. the researcher must sign a pledge of confidentiality;

- e. when the random sample has been defined, then consent must be requested from those included in the sample in accordance with paragraph 4 of this Code of Conduct, before their personal data can be used for the investigation. Until that time the selected files remain under the supervision of the care provider.
- 6.4 For the situation described in 6.1 under d, the following additional requirements also apply:
- a. a researcher cannot describe a proposed research project in a protocol without first having access to a limited amount of personal data about a limited number of individuals;
  - b. it makes no sense to request consent from these individuals because it is not possible to describe adequately the investigation for which the consent is being requested;
  - c. access takes place under the supervision of the care provider involved in the treatment;
  - d. no more data will be accessed than is needed for the description of the research question;
  - e. the aim and the time of access are agreed upon in writing beforehand by the care provider and the researcher, and the researcher signs a pledge of confidentiality.

If this is the situation, then the research protocol cannot have been reviewed positively. Articles 4.4 and 6.2 under a are therefore not applicable in this situation.

**7. Special measures for the use of directly identifying personal data**

*7.1 Differentiation between communication data and research data*

In the course of processing directly identifying personal data, a distinction should be made insofar as possible between a database of communication data for the one involved and a database of research data. Coupling between the two occurs by means of a meaningless administration number.

The regulations for access and the possibilities for processing the communication data and the research data should differ. For this purpose, adequate safety measures must be taken.

*7.2 Storage of personal data*

If no distinction is made between communication data and research data, as described in 7.1, then the data must be destroyed as soon as reasonably can be predicted that it will no longer be need for this investigation.

If a communication file has been created, then this file should be removed as soon as it is no longer needed for this investigation. What then is left over for the researcher is a database without directly identifying data.

This may only be stored for as long as can reasonably be predicted that it will be needed for a health research project.

*7.3 Rights of the data subject*

If directly identifying personal data are processed, the data subject has the right to access, the right to correction and the right to block or remove data which are directly related to him. The researcher can decide, if the data subject wants to make or has made use of this right to correct or block data, to convert the personal data into anonymous data.



## 8. Complaints

The researcher makes sure that the person whose data is to be used in the investigation is aware of the possibility to lodge a complaint about the lack of compliance with the aforementioned rules of conduct. If necessary the researcher will provide information about the available possibilities, such as:

- submit a complaint to the directors of the (research) institution;
- submit a complaint to a committee for complaints in health care
- submit a complaint to the Complaints Committee of the Foundation for the Federation of Medical Scientific Societies.
- submit a request for an investigation by the Data Protection Authority on the basis of WBP;
- take the judicial route

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