Questionnaire on the implementation of Recommendation 97(5) in current member states

Section 1. Overview of Legal Architecture and Legislative Instruments Regarding Data Protection and Medical Data, Definitions and Scope

Q.1.1 How is 'personal data' defined in your domestic law? Please cite sources.	
Legislation:	
Jurisprudence/Case-law:	

Q.1.2 Does the legislation define medical/health data as a separate category of personal data/does the legislation define those data as a sensitive data?	
Yes	No
Q.1.2.1 If yes, how is medical/health data defined? Please cite sources.	
Legislation:	
Jurisprudence/Case-law:	

Q.1.3 Does the legislation define 'genetic data' as a separate category of personal data?	
Yes	No
Q.1.3.1 If yes, how is 'genetic data' defined?	
Legislation:	
Jurisprudence/Case-law:	

Q.1.4 Are there body or bodies is/are responsible for overseeing data protection in your country?	
Yes	No
Q.1.4.1 If yes, please list the body or bodies responsible for overseeing data protection in your country.	
Q.1.4.2 If there are different bodies responsible for overseeing data protection do these bodies overlap in competence?	
Yes	No
Q.1.4.3 If yes, please list the field of competences.	
Q.1.4.4 How many data breaches were reported to this authority in the last five years?	
Q.1.4.5 How many of those data breaches were reported to this authority in the last five years pertained to medical data?	

Section 2. Respect for Privacy and the Collection of Medical Data

Q.2.1 Does the legislation require any specific reason for collecting or processing medical data?	
Yes	No
Q.2.1.1 If yes, please list the reasons.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.2 Does the legislation provide the principle of medical data quality (minimization, accuracy, etc.)?	
Yes	No
Q.2.2.1 If yes, please list the principles.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.3Does the legislation specify who may or may not collect or process medical data?	
Yes	No
Q.2.3.1 If yes, please list the individuals/bodies.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.3 Does the legislation propose or detail any specific safeguards for collecting or processing medical data?	
Yes	No

Q.2.3.1 If yes, please list the safeguards.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.3.2 Does the legislation require a specific identifier for patients ?	
Yes	No

Q.2.3.3 If yes, please explain in further detail how the identifier is given and any further rules.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.4 Does the legislation provide processing medical/health data in electronic medical files?	
Yes	No

Q.2.4.1 If yes, please describe legal prerequisites for processing data in such files (i.a. who is the controller of the files, are the files centralized?).	
Legislation:	
Jurisprudence/Case-law:	

Q.2.5 Are there any technical guidelines provided for the processing of medical data?	
Yes	No

Q.2.5.1 If so, please list the titles of guidelines and the publishing body.	

Q.2.6 Please list the legal grounds for processing medical data.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.7. Does the legislation specify from whom medical data may be obtained (e.g, the data subject and those apart from the data subject)?	
Yes	No

Q.2.7.1 If yes, please individuals or bodies from whom medical data may be obtained.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.7.2 Does the legislation explain the reasons why the medical data may be obtained from the individual as well as sources other than the individual?	
Yes	No

Q.2.7.3 If yes, please identify those reasons.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.8 Does the legislation make any specific reference to the medical data pertaining to foetuses/unborn children?	
Yes	No

Q.2.8.1 If yes, please explain the provisions and the context.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.8.2 Who is entitled to act for unborn children/foetuses in your national legislation? Please answer.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.9. Does the legislation specify any purposes for which genetic data may be used?	
Yes	No

Q.2.9.1 If yes, what conditions need to be satisfied in order to collect/use genetic data?	
Legislation:	
Jurisprudence/Case-law:	

Q.2.9.2 Does the legislation allow for use of genetic data in criminal investigations?	
Yes	No

Q.2.9.3 If yes, how may genetic data be used in a judicial procedure or in a criminal investigations according to the legislation?	
Legislation:	
Jurisprudence/Case-law:	

Q.2.9.4 Does the legislation specify any particular safeguards for genetic data in criminal investigations?	
Yes	No

Q.2.9.5 If yes, what specific safeguards are defined in the legislation?	
Legislation:	
Jurisprudence/Case-law:	

Q.2.9.6 Does the legislation provide for the use of genetic data in predicting illness?	
Yes	No

Q.2.9.7 If yes, please describe how genetic data may be used and in what circumstances.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.9.8 Does the legislation specify what will happen with the information of the prenatal diagnosis after the birth of the children?	
Yes	No

Q.2.9.9 If yes, please describe how the information is used and stored and in what circumstances.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.10. Does the legislation address the use of genetic data in the context of profiling?	
Yes	No
Q.2.10.1 If yes, what conditions need to be satisfied in order to collect/use genetic data?	
Legislation:	
Jurisprudence/Case-law:	

Section 3. Information of the Data Subject

Q.3.1. Does the law specify what information the data controller must provide to the data subject?	
Yes	No
Legislation/ Caselaw:	
Q.3.1.1 If yes, list and describe briefly all kinds of information.	
Legislation:	
Jurisprudence/Case-law:	

Q.3.2. Are the data subjects informed, prior to genetic analysis, about the objectives of the analysis and the possibility of unexpected findings?	
Yes	No
Legislation/ Caselaw:	
Q.3.2.1 If yes, does the law specify the manner by which the data subject is to be informed about the objectives of the analysis and the possibility of unexpected findings?	
Yes	No
Legislation/ Caselaw:	

Q.3.3. Does the law specify how information is to be given to data subjects who are legally incapacitated, incapable of free decision or in any other case where the law does not permit the data subject to act on his/her own behalf?	
Yes	No
Legislation/ Caselaw:	
Q.3.3.1 If yes, please describe how this information is provided to incapacitated individuals.	
Legislation:	
Jurisprudence/Case-law:	
Q.3.3.2 Does the law make a distinction between those individuals who are capable of	

understanding and those who do not?	
Yes	No
Legislation/ Caselaw:	

Q.3.3.3 If yes, does this distinction have any legal ramifications?	
Yes	No
Legislation/ Caselaw:	

Q.3.3.4 If yes, please describe these ramifications.	
Legislation:	
Jurisprudence/Case-law:	

Q.3.4. Does the law specify instances or circumstances wherein the access, notification and other information rights of the data subject may be derogated from?	
Yes	No
Legislation/ Caselaw:	

Q.3.4.1 If yes, please describe the circumstances which provide for such derogation.	
Legislation:	
Jurisprudence/Case-law:	

Q.3.5. Does the law specify when the data subject is to be informed of the collection and its effects?	
Yes	No
Legislation/ Caselaw:	

Q.3.5.1 If yes, please describe when the law specifies this moment of information.	
Legislation:	
Jurisprudence/Case-law:	

Q.3.5.2 Does the law allow for the data controller to adapt the information given to data subject so that it may be appropriate for the circumstances?	
Yes	No
Legislation/ Caselaw:	

Q.3.5.3 If yes, please describe how the data controller may adapt information and in what circumstances.	
Legislation:	
Jurisprudence/Case-law:	

Q.3.6 Does the law specify how, if or when relatives of the data subject can / must be informed about the results of an analysis ?	
Yes	No
Q.3.6.1 If yes, please describe this in further detail, specifically the circumstances and rules regarding such information of an analysis.	
Legislation:	
Jurisprudence/Case-law:	

Section 4. Consent

Q.4.1. Does the law provide a definition of consent?	
Yes	No
Legislation/ Caselaw:	
Q.4.1.1 If yes, please provide the definition.	
Legislation:	
Jurisprudence/Case-law:	

Q.4.2. Does the law provide a separate definition of consent in the context of data processing?	
Yes	No
Legislation/ Caselaw:	
Q.4.2.1 If yes, please provide the definition.	
Legislation:	
Jurisprudence/Case-law:	

Q.4.3. Does the law provide a specific mechanism for obtaining valid consent?	
Yes	No
Legislation/ Caselaw:	

Q.4.3.1 If yes, please describe the mechanism in the law.	
Legislation:	
Jurisprudence/Case-law:	

Q.4.4. Does the law provide that medical data may be collected or processed without the consent of the data subject/ ?	
Yes	No
Legislation/ Caselaw:	

Q.4.4.1 If yes, please describe the instances wherein medical data may be processed without the data subject's consent.	
Legislation:	
Jurisprudence/Case-law:	

Q.4.5 Is it possible for the data subject to refuse consent with regards to the collection and processing of medical data?	
Yes	No
Legislation/ Caselaw:	

Q.4.6 Is it possible for the data subject to withdraw consent to medical data processing after having provided such consent ?	
Yes	No
Legislation/ Caselaw:	

Q.4.7 In the event that genetic analysis is carried out, is the data subject informed of all and any results that arise or only those results deriving from the purpose for which the data subject has consented?	
Yes	No
Legislation/ Caselaw:	

Q.4.8 Does the law allow for minors to consent to medical data processing without a parent/guardian?	
Yes	No
Legislation/ Caselaw:	

Q.4.9 If a person is deemed 'capable of understanding', is this person's views taken into account when considering valid consent?	
Yes	No
Legislation/ Caselaw:	

Section 5. Communication of Medical Data

Q.5.1. Does the law allow for an individual's medical data to be communicated to third parties?	
Yes	No
Legislation/ Caselaw:	
Q.5.1.1. If yes, is the data subject informed about such communication?	
Yes	No
Legislation/ Caselaw:	
Q.5.1.2 If yes, is the data subject able to block such communication?	
Yes	No
Legislation/ Caselaw:	
Q.5.1.3 If the data is to be communicated to third parties, does the law specify any defined safeguards?	
Yes	No
Legislation/ Caselaw:	
Q.5.1.4 If yes, please describe the safeguards provided for by law in this situation.	
Legislation:	
Jurisprudence/Case-law:	

Q.5.2 Does the law provide that the rules regarding medical confidentiality may be derogated from in certain instances?	
Yes	No
Legislation/ Caselaw:	
Q.5.2.1. If yes, please explain these circumstances.	
Legislation/ Caselaw:	

Q.52.2. In the above circumstances, does the law provide any additional safeguards?	
Yes	No
Legislation/ Caselaw:	
Q.5.2.3. If yes, please describe these safeguards.	
Legislation/ Caselaw:	

Section 6. Rights of the Data Subject

Q.6.1. Does the law provide that the data subject a right of access to his/her information?	
Yes	No
Legislation/ Caselaw:	

Q.6.2. Does the law provide instances where access to an individual's own medical data may be refused?	
Yes	No
Legislation/ Caselaw:	
Q.6.2.1. If yes, please list these instances.	
Legislation:	
Jurisprudence/Case-law:	
Q.6.2.2. Can such refusal be appealed by the individual?	
Yes	No
Legislation/ Caselaw:	

Q.6.3. Does the law provide that an individual may correct or rectify information in his/her own medical data file?	
Yes	No
Legislation/ Caselaw:	
Q.6.3.1. If yes, does the law specify any procedure for such rectification?	
Yes	No
Legislation/ Caselaw:	
Q.6.3.2. If yes, please describe the procedure for rectification.	
Legislation:	
Jurisprudence/Case-law:	

Q.6.4 Does the law provide that a minor may access his/her own medical data file?	
Yes	No
Legislation/ Caselaw:	

Q.6.4.1 If yes, are there any conditions (e.g. age, competence) that are required by law?	
Yes	No
Legislation/ Caselaw:	

Q.6.4.2 If yes, please describe these conditions.	
Legislation:	
Jurisprudence/Case-law:	

Q.6.4.3. Does the law provide that a minor can prevent his/her parents/guardian from accessing his/her medical data?	
Yes	No
Legislation/ Caselaw:	

Q.6.5. According to the law, are individuals subjected to genetic analysis informed of unexpected results or findings?	
Yes	No
Legislation/ Caselaw:	

Q.6.5.1. Does the law provide that this information may be kept from the individual in certain circumstances?	
Yes	No
Legislation/ Caselaw:	

Q.6.5.2. If yes, please describe these circumstances.	
Legislation/ Caselaw:	

Section 7. Security

Q.7.1. Is breaching privacy (not including data protection) an offense under the law?	
Yes	No
Legislation/ Caselaw:	

Q.7.1.1 If yes, please briefly describe the consequences of such breaching another's privacy.	
Legislation:	
Jurisprudence/Case-law:	

Q.7.2. Does the law have specific provisions relating to breaches of data protection?	
Yes	No
Legislation/ Caselaw:	

Q.7.2.1 If yes, please describe the breaches contemplated by law.	
Legislation:	
Jurisprudence/Case-law:	

Q.7.2.2 Does the law have provide the obligation to notify breaches of data protection?	
Yes	No
Legislation/ Caselaw:	

Q.7.2.3 If yes, please specify the body or bodies responsible for notifying breaches of data protection in your country.

Q.7.3 Does the law have specific provisions relating to penalties regarding breaches of sensitive data?	
Yes	No
Legislation/ Caselaw:	

Q.7.3.1 If yes, please describe these penalties.	
Legislation:	
Jurisprudence/Case-law:	

Q.7.3.2 Are these breaches aggravated in the context of medical data?	
Yes	No
Legislation/ Caselaw:	

Q.7.3.3 If yes, please describe the aggravation and its effects at law.	
Legislation:	
Jurisprudence/Case-law:	

Q.7.4. Does the law provide the obligation to establish individuals responsible for overseeing security of data processing files in specific situations?	
Yes	No
Legislation/ Caselaw:	

Q.7.4.1 If yes, in which situations?

Q.7.4.2 Does this individual need to be independent of the organisation or may this individual be an internal employee?	
Independent	Internal
Legislation/ Caselaw:	

Q.7.5. Does the law specify that controllers of medical data files are to draw up internal regulations for data security?	
Yes	No
Legislation/ Caselaw:	
Q.7.5.1 If yes, are these regulations required to be reviewed?	
Yes	No
Legislation/ Caselaw:	
Q.7.5.2. If yes, at what intervals must the review occur? If there is no time specified, please state this.	
Legislation/ Caselaw:	

Q.7.6 Does the law specify the creation of any national body responsible for the issuing of technical guidance on data processing security?	
Yes	No
Legislation/ Caselaw:	

Section 8. Conservation

Q.8.1 Does the law specify a time limit that medical records may be held by a data controller?

Yes	No

Legislation/ Caselaw:	

Q.8.1.1 If yes, what is the maximum length of time are records of medical data can be held in your country?

Legislation:	
Jurisprudence/Case-law:	

Q.8.1.2 Are there any instances where medical records may be kept longer than prescribed by law? in which medical data is conserved for longer than necessary to achieve the purpose for which they were originally collected and processed?

Yes	No

Legislation/ Caselaw:	

Q.8.1.3 If yes, please describe these circumstances.

Legislation:	
Jurisprudence/Case-law:	

Q.8.1.4. Does the law specify individuals in your country have the right to have their medical data erased?

Yes	No

Legislation/ Caselaw:	

Q.8.1.5. If yes, does the law outline a procedure for erasure?

Yes	No

Legislation/ Caselaw:	

Q.8.1.6 If yes, please describe the procedure.

Legislation:	
Jurisprudence/Case-law:	

Q.8.1.7 If the right to erasure does exist, can an individual's request be refused?

Yes	No

Legislation/ Caselaw:	

Q.8.1.8 If yes, please describe the grounds for refusal.

Legislation:	
Jurisprudence/Case-law:	

Section 9. Transborder Flows

Q.9.1 Does the law regulate trans-border flows of personal data (including medical data)?	
Yes	No
Legislation/ Caselaw:	

Q.9.1.1 If yes, please describe the conditions by which personal data may transferred to another country.	
Legislation:	
Jurisprudence/Case-law:	

Q.9.2 Is your country part to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data?	
Yes	No
Legislation/ Caselaw:	

Q.9.3 Does the law require safeguards when data is to be transferred to another country?	
Yes	No
Legislation/ Caselaw:	

Q.9.3.1 If yes, please describe the safeguards prescribed in the law.	
Legislation:	
Jurisprudence/Case-law:	

Section 10. Scientific Research

Q.10.1 Where medical data is requested for scientific research, is it modified in any way before being passed on to researchers?	
Yes	No
Legislation/ Caselaw:	

Q.10.1.1 If yes, please describe the way in which the data is modified.	
Legislation:	
Jurisprudence/Case-law:	

Q.10.2. Does the law prescribe a particular procedure to request medical data for research purposes?	
Yes	No

Legislation/ Caselaw:	

Q.10.2.1 If yes, please describe the procedure as provided in law.

Legislation:	
Jurisprudence/Case-law:	

Q.10.3. Does the authority/body responsible for data protection in your country provide guidance on making medical data available to researchers?

Yes	No

Legislation/ Caselaw:	

Q.10.3.1 If yes, please provide the title and references to such guidance.

Legislation:	
Jurisprudence/Case-law:	

Q.10.4. Does the law provide that If anonymisation of the records makes a scientific research project impossible, that the consent from the data subject may be sought?

Yes	No

Legislation/ Caselaw:	

Q.10.4.1 If yes, does the law specify a procedure by which to gain consent for scientific research?

Yes	No

Legislation/ Caselaw:	

Q.10.4.2 If yes, please describe the procedure as provided in law.

Legislation:	
Jurisprudence/Case-law:	

Q.10.5. If the individual cannot be reached to provide consent, may the information still be used?

Yes	No

Legislation/ Caselaw:	

Q.10.6 Does the law specify that the individual is to be informed of the nature and purpose of the scientific research?

Yes	No

Legislation/ Caselaw:	

Q.10.7 Does the law identify any research objectives which would override the need for a data subject's consent?	
Yes	No
Legislation/ Caselaw:	

Q.10.8 Does the law allow healthcare professionals allowed to use medical data they already have access to by way of their role for research?	
Yes	No
Legislation/ Caselaw:	
Q.10.8.1 If yes, is additional consent of the data subject required?	
Yes	No
Legislation/ Caselaw:	
Q.10.8.2 Does the law prescribe a particular procedure to request such consent?	
Yes	No
Legislation/ Caselaw:	
Q.10.8.3 If yes, please describe the procedure as provided in law.	
Legislation:	
Jurisprudence/Case-law:	

Q.10.9 Does the law stipulate that medical data in publications must be anonymised?	
Yes	No
Legislation/ Caselaw:	
Q.10.9.1 If yes, can this stipulation be overridden by gaining the individual's consent?	
Yes	No
Legislation/ Caselaw:	

Other Comment

Should you wish to describe a feature of the medical data protection regime that has not been covered by the questionnaire, please feel free to use the space provided below. Please cite and attach any legislation or policy document: