

**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. Does the legislation in your jurisdiction specifically address data protection?

Yes

No

Q.1.1 If yes, please list the relevant legislation or case-law below.

Q.1.2 Does the protection include the automatic processing of data?

Yes

No

Q.1.2.1 If yes, please list the relevant section below.

Q.1.3 Does your country define 'personal data'?

Yes

No

Q.1.3.1 If yes, how is 'personal data' defined ? Please cite sources in the spaces provided.

Legislation:

Jurisprudence/Case-law:

Q.1.4 Does the legislation define medical/health data as a separate category of personal data?

Yes

No

Q.1.4.1 If so, how is medical/health data defined? Please cite sources in the spaces provided.

Legislation:

Jurisprudence/Case-law:

Q.1.5 Does the legislation define 'genetic data' as a separate category of personal data?	
Yes	No
Q.1.5.1 If so, how is 'genetic data' defined?	
Legislation:	
Jurisprudence/Case-law:	

Q.1.6 Are there body or bodies is/are responsible for overseeing data protection in your country?	
Yes	No
Q.1.6.1 If so, please list the body or bodies responsible for overseeing data protection in your country.	

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
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Q.2.1.1 If yes, please list the reasons in the space provided below

Legislation:	
Jurisprudence/Case-law:	

Q.2.2 Does the legislation specify who may or may not collect or process medical data?

Yes	No
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Q.2.2.1 If so, please list the individuals in the space provided below.

Legislation:	
Jurisprudence/Case-law:	

Q.2.3 Does the legislation propose or detail any specific safeguards for collecting or processing medical data?

Yes	No
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Q.2.3.1 If so, please list the safeguards in the space provided below

Legislation:	
Jurisprudence/Case-law:	

Q.2.4 Are there any technical guidelines provided for the processing of medical data?	
Yes	No
Q.2.4.1 If so, please list the titles of guidelines and the publishing body in the space provided below.	
Q.2.4.2 Please identify the safeguards in the space provided below.	
Q.2.5. Does the legislation specify that data subject's consent is required to process medical data ?	
Yes	No
Q.2.5.1 Does the legislation provide other means by which to collect and process an individual's medical data ?	
Yes	No
Q.2.5.2 If yes, please list the others legally valid means by which to collect and process medical data in the space below.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.6. Does the legislation specify from whom medical data may be obtained?	
Yes	No
Q.2.6.1 If yes, please individuals or bodies from whom medical data may be obtained in the space below.	
Legislation:	
Jurisprudence/Case-law:	
Q.2.6.2 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.2.6.3 If yes, please identify those reasons in the space below.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.7 Does the legislation make any specific reference to the medical data pertaining to fetuses/unborn children ?	
Yes	No
Q.2.7.1 If yes, please explain the provisions and the context in the space below.	
Legislation:	
Jurisprudence/Case-law:	
Q.2.7.2 Who is entitled to act for unborn children/fetuses in your national legislation? Please answer in the space provided below.	
Legislation:	
Jurisprudence/Case-law:	

Q.2.8. Does the legislation specify any purposes for which genetic data may be used?	
Yes	No
Q.2.8.1 If yes, what conditions need to be satisfied in order to collect/use genetic data?	
Legislation:	
Jurisprudence/Case-law:	
Q.2.8.2 Does the legislation allow for use of genetic data in criminal investigations?	
Yes	No
Q.2.8.3 If yes, how may genetic data be used in criminal investigations according to the legislation?	
Legislation:	
Jurisprudence/Case-law:	
Q.2.8.4 Does the legislation specify any particular safeguards for genetic data in criminal investigations?	
Yes	No
Q.2.8.5 If yes, what specific safeguards are defined in the legislation?	
Legislation:	
Jurisprudence/Case-law:	

Q.2.8.6 Does the legislation provide for the use of genetic data in predicting illness?	
Yes	No
Q.2.8.7 If yes, please describe how genetic data may be used and in what circumstances in the space provided below.	
Legislation:	
Jurisprudence/Case-law:	

Section 3. Information of the Data Subject

Q.3.1. Does the law provide that the data subject is to be informed that a file exists containing his/her medical data?

Yes		No	
Legislation/ Caselaw:			
Q.3.1.1 If yes, does the law specify only the existence of the medical data or does the patient have access to the information?			
Legislation:			
Jurisprudence/Case-law:			

Q.3.2. Does the law provide that the data subject is to be informed regarding the purposes for which his/her medical data will be processed?

Yes		No	
Legislation/ Caselaw:			

Q.3.3. Does the law provides that medical data may be collected from sources other than the data subject him/herself?

Yes		No	
Legislation/ Caselaw:			

Q.3.4. If yes, does the law provide that the data subject is be informed from which individuals or bodies this information is collected?

Yes		No	
Legislation/ Caselaw:			

Q.3.5. Does the law provide that the data subject is to be informed about to whom and the purposes for which his/her medical data may be communicated?

Yes		No	
Legislation/ Caselaw:			

Q.3.6. 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.3.6.1 If yes, does the law provide that the data subject is to be informed about the possibility of refusing his/her consent?

Yes	No
Legislation/ Caselaw:	

Q.3.6.2 If yes, does the law provide that data is also to be informed about the consequences of withdrawing consent?

Yes	No
Legislation/ Caselaw:	

Q.3.7. Does the law provide that the data subject is to be informed about the identity of the data controller?

Yes	No
Legislation/ Caselaw:	

Q.3.8. Does the law provide that the data subject a right of access to his/her information?

Yes	No
Legislation/ Caselaw:	

Q.3.8.1 If yes, does the law provide that the data subject is to be informed about the rights of access and of rectification that may be exercised?

Yes	No
Legislation/ Caselaw:	

Q.3.8.2 If yes, does the law specify the manner by which the data subject is to be informed about the rights of access and of rectification that may be exercised?

Yes	No
Legislation/ Caselaw:	

Q.3.9. Are data subjects informed, prior to genetic analysis, about the objectives of the analysis and the possibility of unexpected findings?

Yes	No
Legislation/ Caselaw:	

Q.3.9.1 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.3.10. 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
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Legislation/ Caselaw:

Q.3.10.1 If yes, please describe how this information is provided to incapacitated individuals.

Legislation:

Jurisprudence/Case-law:

Q.3.10.2 Does the law make a distinction between those individuals who are capable of understanding and those who do not?

Yes	No
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Legislation/ Caselaw:

Q.3.10.3 If yes, does this distinction have any legal ramifications?

Yes	No
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Legislation/ Caselaw:

Q.3.10.4 If yes, please describe these ramifications below.

Legislation:

Jurisprudence/Case-law:

Q.3.11. 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
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Legislation/ Caselaw:

Q.3.11.1 If yes, please describe the circumstances which provide for such derogation.

Legislation:

Jurisprudence/Case-law:

Q.3.12. Does the law specify when the data subject is to be informed of the collection and its effects?

Yes	No
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Legislation/ Caselaw:

Q.3.12.1 If yes, please describe when the law specifies this moment of information.

Legislation:	
Jurisprudence/Case-law:	
Q.3.12.2 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.3.12.3 If yes, please describe how the data controller may adapt information and in what circumstances.	
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 in the space provided below.			
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 withdraw consent to medical data processing after having provided such consent ?

	Yes		No
Legislation/ Caselaw:			

Q.4.6 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.4.7 Does the law allow for minors to consent to medical data processing without a parent/guardian?

	Yes		No
Legislation/ Caselaw:			

Q.4.8 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
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Legislation/ Caselaw:

Q.5.1.1. If yes, is the data subject informed about such communication?

Yes	No
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Legislation/ Caselaw:

Q.5.1.2 If yes, is the data subject able to block such communication?

Yes	No
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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
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Legislation/ Caselaw:

Q.5.1.4 If yes, please describe the safeguards provided for by law in this situation.

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Legislation:

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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
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Legislation/
Caselaw:

Q.5.2.1. If yes, please explain these circumstances

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Legislation/
Caselaw:

Q.5.2.2. In the above circumstances, does the law provide any additional safeguards?

Yes	No
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Legislation/
Caselaw:

Q.5.2.3. If yes, please describe these safeguards.

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Legislation/
Caselaw:

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Section 6. Rights of the Data Subject

Q.6.1. Does the law provide instances where access to an individual's own medical data may be refused?

Yes	No
Legislation/ Caselaw:	
Q.6.1.1. If yes, can such refusal be appealed by the individual?	
Yes	No
Legislation/ Caselaw:	

Q.6.2. Does the law provide that an individual may correct or rectify information in his/her own medical data file?

Yes	No
Legislation/ Caselaw:	
Q.6.2.1. If yes, does the law specify any procedure for such rectification?	
Yes	No
Legislation/ Caselaw:	
Q.6.2.2. If yes, please describe the procedure for rectification.	
Legislation:	
Jurisprudence/Case-law:	

Q.6.3 Does the law provide that a minor may access his/her own medical data file?

Yes	No
Legislation/ Caselaw:	
Q.6.3.1 If yes, are there any conditions (e.g. age, competence) that are required by law?	
Yes	No
Legislation/ Caselaw:	
Q.6.3.2 If yes, please describe these conditions.	
Legislation:	
Jurisprudence/Case-law:	
Q.6.3.3. Does the law provide that a minor can prevent his/her parents/guardian from accessing his/her medical data?	
Yes	No
Legislation/ Caselaw:	

Q.6.4. According to the law, are individuals subjected to genetic analysis informed of unexpected results or findings?

Yes

No

Legislation/
Caselaw:

Q.6.4.1. Does the law provide that this information may be kept from the individual in certain circumstances?

Yes

No

Legislation/ Caselaw:

Q.6.4.2. 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.7.3 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 specify that large organisations (such as hospitals) are to have individuals responsible for overseeing security of data processing files?

Yes		No	
Legislation/ Caselaw:			
Q.7.4.1 If yes, 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
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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
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Legislation/ Caselaw:

Q.8.1.3 If yes, please describe these circumstances in the space provided below.

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
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Legislation/ Caselaw:

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

Yes	No
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Legislation/ Caselaw:

Q.8.1.6 If yes, please describe the procedure in the space provided below.

Legislation:

Jurisprudence/Case-law:

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

Yes	No
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Legislation/ Caselaw:

Q.8.1.8 If yes, please describe the grounds for refusal in the space provided below.

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:

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