

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.

In accordance with Article 4) paragraph d) of Law N° 18.331 (Ley de Protección de Datos Personales y Acción de Habeas Data) Personal Data means: "any kind of information regarding identified or identifiable natural or legal persons ."

Legislation:	Article 4° of Law N° 18.331.
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Jurisprudence/Case-law:	
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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	
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Q.1.2.1 If yes, how is medical/health data defined? Please cite sources.

Our law defines health data as sensitive data. Consequently in the article 4 paragraph E) of Law N° 18.331, are defined as : “Sensitive data: personal data revealing racial or ethnic origin, political preferences, religious and moral beliefs, trade union membership and information regarding health or sex life.”

By the way, article 4° paragraph D of Decree 414/009, define Personal data related to health, as: health information concerning past, present or future physical or mental health of a person. Among others, are considered health-related data of people referred to their percentage of disability or genetic information

Legislation:	Article 4° paragraph d of Law N° 18.331 and Article 4° paragraph d of Decree N° 414/009
Jurisprudence/Case-law:	

Q.1.3 Does the legislation define ‘genetic data’ as a separate category of personal data?	
	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
Q.1.4.1 If yes, please list the body or bodies responsible for overseeing data protection in your country.	
	Personal Data Control and Regulatory Unit - (Unidad Reguladora y de Control de Datos Personales or URCDP).
Q.1.4.2 If there are different bodies responsible for overseeing data protection do these bodies overlap in competence?	
	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?	
	The Authority is 4 years old and the data breaches number are 247.
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
Q.2.1.1 If yes, please list the reasons.	

No person shall be forced to provide sensitive data. These can only be subject to processing with the express written consent of the data holder.

In accordance with article 18 of Law N° 18.331, Sensitive data can only be collected and subject to processing when involving reasons of general interest authorised by law, or when the requesting body has the legal order to do so. These data can also be processed with statistical or scientific purposes when dissociated from the holders.

Legislation:	Article 18° of Law N° 18.331.
Jurisprudence/Case-law:	

Q.2.2 Does the legislation provide the principle of medical data quality (minimization, accuracy, etc.)?

No

Q.2.2.1 If yes, please list the principles.

There are no specific regulation for medical data quality. However there are some general principles in Law N° 18.331, that applies to data protection, as for example: A) Legality. B) Veracity. C) Purpose. D) Informed previous consent. E) Data security. F) Confidentiality. G) Liability.

Legislation:	Article 5° of Law N° 18.331.
Jurisprudence/Case-law:	

Q.2.3 Does the legislation specify who may or may not collect or process medical data?

Yes

Q.2.3.1 If yes, please list the individuals/bodies.

According with article 19° of Law N° 18.331, public or private health institutions and professionals associated with health sciences may collect and process personal data regarding the physical or mental health of patients that arrive there or that are or have been under their treatment, observing the principles of professional secrecy, specific regulations and what is stated in the data protection law.

Also, sensitive data can only be collected and subject to processing when involving reasons of general interest authorised by law, or when the requesting body has the legal order to do so. These data can also be processed with statistical or scientific purposes when dissociated from the holders.

The formation of databases which store information that directly or indirectly discloses sensitive data shall be prohibited. Except for those belonging to political parties, trade unions, churches, religious creeds, associations, foundations and other non-profit entities, the purpose of which is political, religious, philosophical, trade union, making reference to the racial or ethnic origin, health and sex life, regarding the data of their members or partners, even though the communication of said data shall always require the data holder's previous consent.

Legislation:	Article 19° of Law N° 18.331.
Jurisprudence/Case-law:	

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

No

There are no specific safeguards for health information in the Data Protection Law. However, according to article 10 (Principle of data security), the controller or database user shall take the necessary actions to ensure personal data security and confidentiality. The purpose of said actions shall be to avoid their falsification, loss, unauthorised search or processing, as well as the detection of diversion of information, either intentional or not, whether risks are associated with human action or the technical medium used. Data shall be stored in such a way that allows for the exercise of the right of access by the holder. The registration of personal data in databases that do not meet technical conditions regarding integrity and security shall be prohibited.

Legislation: Article 10° of Law Nº 18.331 .

Jurisprudence/Case-law:

Q.2.3.2 Does the legislation require a specific identifier for patients ?

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?

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?).

There is no specific process. Please, note that according to article 4 paragraph A, of Data Protection Law, "Database": it denotes, without distinction, the organised set of personal data that are subject to treatment or processing, whether or not electronically, whichever the kind of formation, storage, organisation or access.

Legislation: Article 4° paragraph A of Law Nº 18.331.

Jurisprudence/Case-law:

Q.2.5 Are there any technical guidelines provided for the processing of medical data?

No

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

There is no specific process provided in Data Protection Law. However, there is an specific regulation above data security, specified in Article 10 of the Data Protection Law, requiring the data controller to take such measures as may prove necessary to ensure the security and confidentiality of personal data.

Q.2.6 Please list the legal grounds for processing medical data.

Legislation:	Article 10° of Law N° 18.331.
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

Q.2.7.1 If yes, please individuals or bodies from whom medical data may be obtained.

According to Law No. 18.331, health data must be obtained from the holder of personal data by obtaining the written consent information

Legislation:	Article 18° of Law N° 18.331
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

Q.2.7.3 If yes, please identify those reasons.

According to the provisions of articles 5° y 6° (Article 5) Informed consent for data collection and treatment . When requesting the consent for the collection and processing of data , it must be informed so that you know clearly the purpose for which the data will be used , and the type of activity performed by the manager of the database or treatment. Otherwise, the consent shall be void . (Article. 6) - Methods of obtaining consent . Should be provided to the owner a simple, clear and free to manifest suconsentimiento or refusal to process their data. It is understood that duty fulfilled when enabling the holder the choice between two clearly identified , that are not pre-marked in favor or against. It shall be for the database or seek treatment and keep the proof of the existence of consent or refusal to give, by the owner , through any means within the law. The manager of the database or treatment may request the consent through the procedure established in this Article , without prejudice to other forms or modes that offer similar or superior guarantees. Once the period of ten working days after the holder receives data without consent solicitation is revealed, his silence will constitute a refusal .

Legislation:	Article 5° and 6° of Decree 414/009.
Jurisprudence/Case-law:	

Q.2.8 Does the legislation make any specific reference to the medical data pertaining to fetuses/unborn children?

	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.	
There is no specific prevision in Data Protection Law. According to Law No. 18.426 (DEFENDING THE RIGHT TO SEXUAL AND REPRODUCTIVE HEALTH) the Uruguayan state is in charge.	
Legislation:	Law No. 18.426
Jurisprudence/Case-law:	

Q.2.9. Does the legislation specify any purposes for which genetic data may be used?	
	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	
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?	
There is no specific prevision in Data Protection Law. According to law N° 18.849, Home Office was created as a dependency and Criminal Identification Division of the National Technical Police, the National Registry of Genetic Footprints. In accordance, the National Registry of Genetic Footprints retain and safeguard genetic information obtained pursuant to the provisions of this Act, for the purpose of its use by the procedures and for the purposes set out in the law.	
Legislation:	Law N° 18.849
Jurisprudence/Case-law:	
Q.2.9.4 Does the legislation specify any particular safeguards for genetic data in criminal investigations?	
	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?	
	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?	
	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?	
	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	
Legislation/ Caselaw:	
Q.3.1.1 If yes, list and describe briefly all kinds of information.	
<p>According to article 13° of Data Protection Law, "Right of information regarding data collection" : Whenever personal data are collected, their holders shall be previously informed in an express, accurate and unequivocal way on:</p> <p>A) The purpose for which data shall be processed and who may be the recipients or categories of recipients of the data.</p> <p>B) The existence of the corresponding database, whether electronic or any other type, and the identity and address of its controller.</p> <p>C) Whether replies to the proposed questionnaire are obligatory or voluntary, particularly regarding sensitive</p> <p>D) Consequences of the provision of data and of the refusal to do so, or their inaccuracy.</p> <p>E) The holder's possibility of exercising the right of access and the right to rectify and delete data.</p>	

Legislation:	Article 13° of law N° 18.331
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?

	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?

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?

	No
Legislation/ Caselaw:	The rights and duties of patients are regulated by Law N°. 18.335 which contains provisions on the matter.

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?

	No
Legislation/ Caselaw:	

Q.3.3.3 If yes, does this distinction have any legal ramifications?

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?

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

According to article 13° of Data Protection Law, “Right of information regarding data collection” : Whenever personal data are collected, their holders shall be previously informed in an express, accurate and unequivocal way on:

A) The purpose for which data shall be processed and who may be the recipients or categories of recipients of the data.

B) The existence of the corresponding database, whether electronic or any other type, and the identity and address of its controller.

C) Whether replies to the proposed questionnaire are obligatory or voluntary, particularly regarding sensitive

D) Consequences of the provision of data and of the refusal to do so, or their inaccuracy.

E) The holder’s possibility of exercising the right of access and the right to rectify and delete data.

Legislation:	Article 13° of law N° 18.331
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Jurisprudence/Case-law:	
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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?

	No
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Legislation/ Caselaw:	
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Q.3.5.3 If yes, please describe how the data controller may adapt information and in what circumstances.

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Legislation:	
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Jurisprudence/Case-law:	
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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 ?

	No
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Q.3.6.1 If yes, please describe this in further detail, specifically the circumstances and rules regarding such information of an analysis.

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Legislation:	
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Jurisprudence/Case-law:	
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Section 4. Consent

Q.4.1. Does the law provide a definition of consent?

Yes	
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Legislation/ Caselaw:	
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Q.4.1.1 If yes, please provide the definition.

According to article 4 paragraph c) of Data Protection Law, holder's consent refers to: any free, unequivocal, specific and informed expression of will, by which the holder allows the processing of his/her personal data.

Legislation:	Article 4 paragraph of Law N° 18.331
Jurisprudence/Case-law:	

Q.4.2. Does the law provide a separate definition of consent in the context of data processing?

	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	
Legislation/ Caselaw:	

Q.4.3.1 If yes, please describe the mechanism in the law.

Personal data processing shall be legal whenever the holder has given his/her previous free consent, express and informed, which has to be documented.

Legislation:	Article 9° of Law N° 18.331
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	
Legislation/ Caselaw:	

Q.4.4.1 If yes, please describe the instances wherein medical data may be processed without the data subject's consent.

Involving personal data regarding health and being necessary due to reasons of public health and hygiene, emergency or for the performance of epidemiological studies, as long as the identity of the data holder is protected through adequate dissociation mechanisms.

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	
Legislation/ Caselaw:	Law N° 18.331

Q.4.6 Is it possible for the data subject to withdraw consent to medical data processing after having provided such consent ?

Yes	
Legislation/ Caselaw:	Law N° 18.331

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?

	No
Legislation/ Caselaw:	

Q.4.8 Does the law allow for minors to consent to medical data processing without a parent/guardian?

	No
Legislation/ Caselaw:	The rights and duties of patients are regulated by Law N°. 18.335 which contains provisions on the matter.

Q.4.9 If a person is deemed 'capable of understanding', is this person's views taken into account when considering valid consent?

	No
Legislation/ Caselaw:	The rights and duties of patients are regulated by Law N°. 18.335 which contains provisions on the matter.

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	
Legislation/ Caselaw:	<p>According with article N° 17. Rights regarding data communication.- Personal data subject to processing shall only be communicated for the fulfilment of the purposes directly related to the legitimate interest of the issuer and the recipient, and with the data holder's previous consent, who must be notified of the purpose of the communication, and the recipient, or the elements allowing for the recipient's identification, must be identified.</p> <p>Previous consent for the communication may be revoked. Previous consent shall not be necessary when:</p> <p>A) Thus provided for by a law of general interest. B) Involving the scenarios of article 9 of this law. C) Involving personal data regarding health and being necessary due to reasons of public health and hygiene, emergency or for the performance of epidemiological studies, as long as the</p>

	<p>identity of the data holder is protected through adequate dissociation mechanisms.</p> <p>D) A procedure for the dissociation of information is implemented, so that the holders of the data cannot be identified.</p> <p>The recipient shall be under the same legal and regulatory obligations as the issuer, and the latter shall be jointly and severally liable for their compliance before the control entity and the holder of the involved data.</p>
Q.5.1.1. If yes, is the data subject informed about such communication?	
Yes	
Legislation/ Caselaw:	Please consider the response of point number Q.5.1 (previous).
Q.5.1.2 If yes, is the data subject able to block such communication?	
	No
Legislation/ Caselaw:	Please consider the response of point number Q.5.1 (previous).
Q.5.1.3 If the data is to be communicated to third parties, does the law specify any defined safeguards?	
	No
Legislation/ Caselaw:	According with article N° 10 (Principle of data security), the controller or database user shall take the necessary actions to ensure personal data security and confidentiality. Please note article N° 10 of Law N° 18.331.
Q.5.1.4 If yes, please describe the safeguards provided for by law in this situation.	
Legislation:	Article N° 10 of Law N° 18.331
Jurisprudence/Case-law:	

Q.5.2 Does the law provide that the rules regarding medical confidentiality may be derogated from in certain instances?	
	No
Legislation/ Caselaw:	
Q.5.2.1. If yes, please explain these circumstances.	
Legislation/ Caselaw:	
Q.5.2.2. In the above circumstances, does the law provide any additional safeguards?	
	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	
Legislation/ Caselaw:	Article N° 14 of Law N° 18.331

Q.6.2. Does the law provide instances where access to an individual's own medical data may be refused?

	No
Legislation/ Caselaw:	The rights and duties of patients are regulated by Law N°. 18.335 which contains provisions on the matter.

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?

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	
Legislation/ Caselaw:	According to article 15 of Law N° 18.331. "Right to rectify, update, inclusion or deletion", any natural or legal person shall have the right to request the rectification, updating, inclusion or deletion of their personal data included in a database, when verifying an error, falseness or exclusion in the information which the person is the holder of. The exercise of this right should be analyzed case by case, according to the data subject to rectification.

Q.6.3.1. If yes, does the law specify any procedure for such rectification?

Yes	
Legislation/ Caselaw:	According to article 15° of Data Protection law, the controller shall proceed to carry out the rectification, updating, inclusion or deletion, through the operations required for such purpose within a maximum term of five working days after receiving the request by the data holder or, otherwise, shall state the reasons why he/she/it considers it is not appropriate to do so. If the controller fails to comply with this obligation or upon the expiry of the deadline, the holder of the data shall be authorised to file the writ of habeas data provided for in this law. The erasure or deletion of personal data shall not proceed, except in cases of:

	<p>A) Damages to the rights and legitimate interests of third parties. B) Obvious error or falseness. C) Contravention of a legal obligation.</p> <p>During the process of verification, rectification or inclusion of personal data, the controller, upon third parties' request to access reports on such data, shall record the fact that said information is subject to review. In the case of data transfer or communication, the controller must notify the rectification, inclusion or deletion to the recipient within five working days after the data processing is carried out. The rectification, updating, inclusion, erasure or deletion of personal data, when appropriate, shall be carried out free of charge for the holder.</p>
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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?

No

Legislation/ Caselaw:

Q.6.4.1 If yes, are there any conditions (e.g. age, competence) that are required by law?

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?

No

Legislation/ Caselaw:

Q.6.5. According to the law, are individuals subjected to genetic analysis informed of unexpected results or findings?

No

Legislation/ Caselaw:

Q.6.5.1. Does the law provide that this information may be kept from the individual in certain circumstances?

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	
Legislation/ Caselaw:	The Law N° 18.331, contains no criminal sanctions, but sanctions of an administrative nature. Please refer to the answer given in Q.7.2.1
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	
Legislation/ Caselaw:	
Q.7.2.1 If yes, please describe the breaches contemplated by law.	
<p>According to Article N° 35 of Law 18.331, there are: "Penalty authorities", The Control Entity is empowered to apply the following penalty measures to the controllers or processors of the databases whenever the provisions of this law are infringed:</p> <ol style="list-style-type: none"> 1) Warning. 2) Fine amounting to no more than five hundred thousand indexed units. 3) Suspension of the corresponding database. To this effect, AGESIC is empowered to promote the competent jurisdictional entities to suspend the databases, for a period of no more than six working days, for which breach or infringement of the present law has been proven. The events of infringement shall be documented in compliance with legal formalities and the suspension must be decreed within the next three days after the suspension was requested by AGESIC. AGESIC in turn shall be entitled to execute itself the suspension if the Judge fails to deliver within the time limit. <p>In this last situation, if the Judge subsequently denies the suspension, AGESIC must immediately declare it void. The remedies brought against the judicial decision that results in the suspension, shall not result in suspension. AGESIC may require the service of public forces to enforce said judicial decision.</p> <p>The competence of the acting courts shall be established by the regulations of the Judicature Organic Law, No. 15.750 dated June 24, 1985, its amendments and agreements.</p>	
Legislation:	
Jurisprudence/Case-law:	
Q.7.2.2 Does the law have provide the obligation to notify breaches of data protection?	
Yes	
Legislation/ Caselaw:	
Q.7.2.3 If yes, please specify the body or bodies responsible for notifying breaches of data protection in your country.	
<p>According to article N° 34 of Law N° 18.331, the Control Entity must carry out all the necessary actions to comply with the objectives and the remaining provisions of Data Protection law (N°18.331).</p>	

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Q.7.3 Does the law have specific provisions relating to penalties regarding breaches of sensitive data?	
	No
Legislation/ Caselaw:	Please consider the response of point number Q.7.2.1 and Q.2.3 (previous).
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?	
	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?	
	No
Legislation/ Caselaw:	According to article N° 10 of Data Protection Law, please consider the response of point number Q.2.3 (previous). Also, it is considered a safety measure appropriate and highly recommended.
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:	According to article N°10 of Data Protection Law, please consider the response of point number Q.2.3 (previous).

Q.7.5. Does the law specify that controllers of medical data files are to draw up internal regulations for data security?

	No
Legislation/ Caselaw:	According to article N° 10 of Data Protection Law, please consider the response of point number Q.2.3 (previous). Also, it is considered a safety measure appropriate and highly recommended

Q.7.5.1 If yes, are these regulations required to be reviewed?

	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:	
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Q.7.6 Does the law specify the creation of any national body responsible for the issuing of technical guidance on data processing security?

Legislation/ Caselaw:	According to Article 149 of Law N° 18.719 , was created in the Agency for the Development of Electronic Government and Information Society and Knowledge Management of Information Security that will house the National Response Center Security Incident Computing (CERTuy).

Section 8. Conservation

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

Yes	
Legislation/ Caselaw:	In accordance with the provisions of article N° 8. Principle of purpose.- Data subject to processing shall not be used for purposes other than or incompatible with those motivating their collection. Data shall be deleted whenever they cease to be necessary or relevant for the purposes for which they were collected. The regulations shall determine cases and procedures in which, exceptionally, and considering historical, statistic or scientific values, and according to specific legislation, personal data shall be kept even when said need or appropriateness have expired. Data shall not be communicated between databases, without it being stated by law or without the informed previous consent of the holder.

	Please consider the specific regulation for the preservation of medical records is regulated by Decree 396/003.
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:	Please note Decree N° 396/003.
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
Legislation/ Caselaw:	
Q.8.1.3 If yes, please describe these circumstances.	
Legislation:	Please note Decree N° 396/003.
Jurisprudence/Case-law:	
Q.8.1.4. Does the law specify individuals in your country have the right to have their medical data erased?	
	No
Legislation/ Caselaw:	The rights and duties of patients are regulated by Law N°. 18.335 which contains provisions on the matter.
Q.8.1.5. If yes, does the law outline a procedure for erasure?	
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?	
	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
Legislation/ Caselaw:	Article N° 23 of Law 18.331
Q.9.1.1 If yes, please describe the conditions by which personal data may transferred to another country.	

According to article N° 23 of Data Protection Law about “Data transferred internationally”.– It is prohibited to transfer personal data of whatever kind to countries or international organizations not offering the proper protection in accordance with the standards of International or Regional Law in this matter. This prohibition does not apply in the cases of:

- 1) International judicial cooperation, in accordance with the corresponding international instrument, this being either a Treaty or a Convention, with the particular circumstances under consideration.
- 2) Exchange of medical information, whenever required for the treatment of the patients either for health or public hygiene reasons.
- 3) Bank or stock exchange transactions, pertaining the respective transactions and in accordance with the applicable legislation.
- 4) Agreements within the framework of international treaties agreed upon by the Oriental Republic of Uruguay.
- 5) International cooperation among intelligence organizations to fight against organised crime, terrorism and drugs trade. International transference of data may also be possible in the scenarios mentioned below:
 - A) The interested party has given his/her unmistakable consent to the intended transference.
 - B) The transference is required to execute a contract between the interested party and the data processor or to execute precontractual measures taken at the interested party's request.
 - C) The transference is required to enter into or execute a contract entered into, or to be entered into on behalf of the interested party, between the data processor and a third party.
 - D) The transference is required or demanded by law to protect a major public interest, or to acknowledge, exercise or defend a right in a judicial procedure.
 - E) The transference is required to protect the vital interest of the interested party.
 - F) The transference takes place from a registry, which is created, by virtue of legal or regulatory provisions, to release information to the public and receive queries from the general public or from any person who may prove has a legitimate interest, as long as the conditions established by law for the query are met, for each particular case.

Without prejudice to the provisions of the first paragraph of this article, the Personal Data Control and Regulatory Unit may authorize one transference or a number of transfereces of personal data to a third country which does not guarantee the proper protection, if the processor offers the necessary guarantees for the protection of private life, of essential rights and freedoms of people, as well as guarantees for the exercise of their respective rights. Said guarantees may stem from the corresponding contractual clauses.

Legislation:	Article N° 23 of Law 18.331
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	
Legislation/ Caselaw:	Law 19.030 (Ratifies Convention N° 108 -)Convention for the protection of persons with respect to automatic data processing personal and its additional protocol) .

Q.9.3 Does the law require safeguards when data is to be transferred to another country?

Yes	
Legislation/ Caselaw:	Article N° 23 of Law 18.331

Q.9.3.1 If yes, please describe the safeguards prescribed in the law.

Yes	
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Legislation:	Article N° 23 of Law 18.331
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	
Legislation/ Caselaw:	According to article 18 of Personal data Law, sensitive data can be collected and subjected to treatment for compelling reasons of general interest authorized by law, or when the applicant organization has a legal mandate to do so. They can also be treated with statistical or scientific purposes when disassociated from their holders.

Q.10.1.1 If yes, please describe the way in which the data is modified.

Legislation:	Article 18 of Law 18.331
Jurisprudence/Case-law:	

Q.10.2. Does the law prescribe a particular procedure to request medical data for research purposes?

	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?

	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	
Legislation/ Caselaw:	Article 18 of Law 18.331

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

Yes	
Legislation/ Caselaw:	Article 18 of Law 18.331
Q.10.4.2 If yes, please describe the procedure as provided in law.	
Legislation:	Article 18 of Law 18.331
Jurisprudence/Case-law:	

Q.10.5. If the individual cannot be reached to provide consent, may the information still be used?	
	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	
Legislation/ Caselaw:	Please note answer given in Q.3.5

Q.10.7 Does the law identify any research objectives which would override the need for a data subject's consent?	
	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	
Legislation/ Caselaw:	According to article 18 of Personal data Law, sensitive data can be collected and subjected to treatment for compelling reasons of general interest authorized by law, or when the applicant organization has a legal mandate to do so. They can also be treated with statistical or scientific purposes when disassociated from their holders.
Q.10.8.1 If yes, is additional consent of the data subject required?	
Yes	
Legislation/ Caselaw:	Article 18 of Law N° 18.331 .
Q.10.8.2 Does the law prescribe a particular procedure to request such consent?	
Yes	
Legislation/ Caselaw:	Article 18 of Law N° 18.331 .
Q.10.8.3 If yes, please describe the procedure as provided in law.	
Personal data processing must be legal whenever the holder has given his/her previous free consent, express and informed, which has to be documented.	
Legislation:	Law N° 18.331
Jurisprudence/Case-law:	

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