

Data Protection: European Directive and National Legislation (UK, FR, CZ, I, D):

I. European Directive 95/46

important articles in terms of informed consent and anonymization:

Article 6

1. Member States shall provide that personal data must be:

- (a) processed fairly and lawfully;
- (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards;
- (c) adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed;
- (d) accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified;
- (e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use.....

Article 8

The processing of special categories of data

1. Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.

2. Paragraph 1 shall not apply where:

- (a) the data subject has given his explicit consent to the processing of those data, except where the laws of the Member State provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject's giving his consent; or
- (b) processing is necessary for the purposes of carrying out the obligations and specific rights of the controller in the field of employment law in so far as it is authorized by national law providing for adequate safeguards; or
- (c) processing is necessary to protect the vital interests of the data subject or of another person where the data subject is physically or legally incapable of giving his consent; or
- (d) processing is carried out in the course of its legitimate activities with appropriate guarantees by a foundation, association or any other non-profit-seeking body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely

to the members of the body or to persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects; or

(e) the processing relates to data which are manifestly made public by the data subject or is necessary for the establishment, exercise or defence of legal claims.

3. Paragraph 1 shall not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.

5. Processing of data relating to offences, criminal convictions or security measures may be carried out only under the control of official authority, or if suitable specific safeguards are provided under national law, subject to derogations which may be granted by the Member State under national provisions providing suitable specific safeguards. However, a complete register of criminal convictions may be kept only under the control of official authority.

Member States may provide that data relating to administrative sanctions or judgements in civil cases shall also be processed under the control of official authority.

6. Derogations from paragraph 1 provided for in paragraphs 4 and 5 shall be notified to the Commission.

7. Member States shall determine the conditions under which a national identification number or any other identifier of general application may be processed.

Article 9

Processing of personal data and freedom of expression

Member States shall provide for exemptions or derogations from the provisions of this Chapter, Chapter IV and Chapter VI for the processing of personal data carried out solely for journalistic purposes or the purpose of artistic or literary expression only if they are necessary to reconcile the right to privacy with the rules governing freedom of expression.

Article 17

Security of processing

1. Member States shall provide that the controller must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

Having regard to the state of the art and the cost of their implementation, such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected.

2. The Member States shall provide that the controller must, where processing is carried out on his behalf, choose a processor providing sufficient guarantees in respect of the technical

security measures and organizational measures governing the processing to be carried out, and must ensure compliance with those measures.

3. The carrying out of processing by way of a processor must be governed by a contract or legal act binding the processor to the controller and stipulating in particular that:

- the processor shall act only on instructions from the controller,
- the obligations set out in paragraph 1, as defined by the law of the Member State in which the processor is established, shall also be incumbent on the processor.

4. For the purposes of keeping proof, the parts of the contract or the legal act relating to data protection and the requirements relating to the measures referred to in paragraph 1 shall be in writing or in another equivalent form.

II. National Legislation

(source: http://ec.europa.eu/justice_home/fsj/privacy/law/implementation_en.htm)

UK: Data protection Act 1988

including:

PART I

PRELIMINARY

Section 1.Basic interpretative provisions.

2.Sensitive personal data.

3.The special purposes.

4.The data protection principles.

SCHEDULES:

Schedule 1- The data protection principles.

Schedule 3- Conditions relevant for purposes of the first principle: processing of sensitive personal data.

Czech Republic: Personal Data Protection Act (Act 101 of April 4, 2000)

including:

Article 4
Definition of Terms

For the purposes of this Act:

- a) "personal data" shall mean any information relating to an identified or identifiable data subject. A data subject shall be considered identified or identifiable if it is possible to identify the data subject directly or indirectly in particular on the basis of a number, code or one or more factors specific to his/her physical, physiological, psychical, economic, cultural or social identity;
- b) "sensitive data" shall mean personal data revealing nationality, racial or ethnic origin, political attitudes, trade-union membership, religious and philosophical beliefs, conviction of a criminal act, health status and sexual life of the data subject, as well as any biometric data of the data subject;
- c) "**anonymous** data" shall mean such data that **cannot be linked** to an identified or identifiable data subject in their original form or following processing.....

Article 5

(1) The controller shall be obliged to:

- (a) specify the purpose for which personal data are to be processed;
- (b) specify the means and manner of personal data processing;
- (c) process only accurate personal data, which he obtained in accordance with this Act. If necessary, the controller is obliged to update the data. If the controller finds that the data being processed thereby are not accurate with respect to the specified purpose, he takes adequate measures without undue delays, in particular he blocks the processing and corrects or supplements the personal data, or otherwise he must liquidate the personal data. Inaccurate personal data may be processed only within the limits of the provisions of Article 3(6) of this Act. Inaccurate personal data must be branded. The controller is obliged to provide all the recipients with the information about blocking, correction, supplementing or liquidation of personal data without undue delay;
- (d) collect personal data corresponding exclusively to the specified purpose and in an extent that is necessary for fulfilment of the specified purpose;
- (e) preserve personal data only for a period of time that is necessary for the purpose of their processing. After expiry of this period, personal data may be preserved only for purposes of the state statistical service, and for scientific and archival purposes. When using personal data for these purposes, it is necessary to respect the right to protection of private and personal life of the data subject from unauthorised interference and to make personal data anonymous as soon as possible...

Article 9

Sensitive Data

Sensitive data may be processed only:

- a) if the data subject has given his express **consent** to the processing. When giving his consent, the data subject must be provided with the information about what purpose of processing, what personal data, which controller and what period of time the consent is being given for. The controller must be able to prove the existence of the consent of data subject to personal data processing during the whole period of processing. The controller is obliged to instruct in advance the data subject of his rights pursuant to Articles 12 and 21,
- b) if it is necessary in order to preserve the life or health of the data subject or some other person or to eliminate imminent serious danger to their property, if

his consent cannot be obtained, in particular, due to physical, mental or legal incapacity, or if the data subject is missing or for similar reasons. The controller shall be obliged to terminate data processing as soon as the above mentioned reasons cease to exist and must liquidate the data, unless the data subject gives his consent to further processing.

c) if the processing in question is in relation with ensuring health care, public health protection, health insurance, and the exercise of public administration in the field of health sector pursuant to a special Act, or it is related to assessment of health in other cases provided by a special Act,

d) if the processing is necessary to keep the obligations and rights of the controller responsible for processing in the fields of labour law and employment provided by a special Act,

e) if the processing pursue political, philosophical, religious or trade-union aims and is carried out within the scope of legitimate activity of a civil association, foundation or other legal person of non-profit nature (hereinafter referred to as the "association"), and which relates only to members of the association or persons with whom the association is in recurrent contact related to legitimate activity of the association, and the personal data are not disclosed without the consent of data subject,

f) if the data processed pursuant to a special Act are necessary to carry on health insurance, social insurance (security), state social support and other state social benefits, social care and social and legal protection of children, and if, at the same time, the protection of these data is ensured in accordance with the law,

g) if the processing concerns personal data published by the data subject, or

h) if the processing is necessary to secure and exercise legal claims.

ch) if they are processed exclusively for archival purposes pursuant to a special Act

France: LOI n° 2004-801 du 6 aout 2004:

including:

Chapitre II

Conditions de licéité des traitements de données
à caractère personnel

Section 1

Dispositions générales

« Art. 6. - Un traitement ne peut porter que sur des données à caractère personnel qui satisfont aux conditions suivantes :

« 1° Les données sont collectées et traitées de manière loyale et licite ;

« 2° Elles sont collectées pour des finalités déterminées, explicites et légitimes et ne sont pas traitées ultérieurement de manière incompatible avec ces finalités. Toutefois, un traitement ultérieur de données à des fins statistiques ou à des fins de recherche scientifique ou

historique est considéré comme compatible avec les finalités initiales de la collecte des données, s'il est réalisé dans le respect des principes et des procédures prévus au présent chapitre, au chapitre IV et à la section 1 du chapitre V ainsi qu'aux chapitres IX et X et s'il n'est pas utilisé pour prendre des décisions à l'égard des personnes concernées ;

« 3° Elles sont adéquates, pertinentes et non excessives au regard des finalités pour lesquelles elles sont collectées et de leurs traitements ultérieurs ;

« 4° Elles sont exactes, complètes et, si nécessaire, mises à jour ; les mesures appropriées doivent être prises pour que les données inexactes ou incomplètes au regard des finalités pour lesquelles elles sont collectées ou traitées soient effacées ou rectifiées ;

« 5° Elles sont conservées sous une forme permettant l'identification des personnes concernées pendant une durée qui n'excède pas la durée nécessaire aux finalités pour lesquelles elles sont collectées et traitées.

« Art. 7. - Un traitement de données à caractère personnel doit avoir reçu le consentement de la personne concernée ou satisfaire à l'une des conditions suivantes :

« 1° Le respect d'une obligation légale incombant au responsable du traitement ;

« 2° La sauvegarde de la vie de la personne concernée ;

« 3° L'exécution d'une mission de service public dont est investi le responsable ou le destinataire du traitement ;

« 4° L'exécution, soit d'un contrat auquel la personne concernée est partie, soit de mesures précontractuelles prises à la demande de celle-ci ;

« 5° La réalisation de l'intérêt légitime poursuivi par le responsable du traitement ou par le destinataire, sous réserve de ne pas méconnaître l'intérêt ou les droits et libertés fondamentaux de la personne concernée.

« Section 2

« Dispositions propres à certaines catégories de données

« Art. 8. - I. - Il est interdit de collecter ou de traiter des données à caractère personnel qui font apparaître, directement ou indirectement, les origines raciales ou ethniques, les opinions politiques, philosophiques ou religieuses ou l'appartenance syndicale des personnes, ou qui sont relatives à la santé ou à la vie sexuelle de celles-ci.

« II. - Dans la mesure où la finalité du traitement l'exige pour certaines catégories de données, ne sont pas soumis à l'interdiction prévue au I :

« 1° Les traitements pour lesquels la personne concernée a donné son consentement exprès, sauf dans le cas où la loi prévoit que l'interdiction visée au I ne peut être levée par le consentement de la personne concernée ;

« 2° Les traitements nécessaires à la sauvegarde de la vie humaine, mais auxquels la personne

concernée ne peut donner son consentement par suite d'une incapacité juridique ou d'une impossibilité matérielle ;

« 3° Les traitements mis en oeuvre par une association ou tout autre organisme à but non lucratif et à caractère religieux, philosophique, politique ou syndical :

« - pour les seules données mentionnées au I correspondant à l'objet de ladite association ou dudit organisme ;

« - sous réserve qu'ils ne concernent que les membres de cette association ou de cet organisme et, le cas échéant, les personnes qui entretiennent avec celui-ci des contacts réguliers dans le cadre de son activité ;

« - et qu'ils ne portent que sur des données non communiquées à des tiers, à moins que les personnes concernées n'y consentent expressément ;

« 4° Les traitements portant sur des données à caractère personnel rendues publiques par la personne concernée ;

« 5° Les traitements nécessaires à la constatation, à l'exercice ou à la défense d'un droit en justice ;

« 6° Les traitements nécessaires aux fins de la médecine préventive, des diagnostics médicaux, de l'administration de soins ou de traitements, ou de la gestion de services de santé et mis en oeuvre par un membre d'une profession de santé, ou par une autre personne à laquelle s'impose en raison de ses fonctions l'obligation de secret professionnel prévue par l'article 226-13 du code pénal ;

« 7° Les traitements statistiques réalisés par l'Institut national de la statistique et des études économiques ou l'un des services statistiques ministériels dans le respect de la loi n° 51-711 du 7 juin 1951 sur l'obligation, la coordination et le secret en matière de statistiques, après avis du Conseil national de l'information statistique et dans les conditions prévues à l'article 25 de la présente loi ;

« 8° Les traitements nécessaires à la recherche dans le domaine de la santé selon les modalités prévues au chapitre IX.

« III. - Si les données à caractère personnel visées au I sont appelées à faire l'objet à bref délai d'un procédé d'anonymisation préalablement reconnu conforme aux dispositions de la présente loi par la Commission nationale de l'informatique et des libertés, celle-ci peut autoriser, compte tenu de leur finalité, certaines catégories de traitements selon les modalités prévues à l'article 25. Les dispositions des chapitres IX et X ne sont pas applicables.

« IV. - De même, ne sont pas soumis à l'interdiction prévue au I les traitements, automatisés ou non, justifiés par l'intérêt public et autorisés dans les conditions prévues au I de l'article 25 ou au II de l'article 26.

(there is an English translation at <http://www.cnil.fr/>)

Hungary: Act LXIII of 1992 on the Protection of Personal Data and Public Access to Data of Public Interest

including:

Article 5

(1) Personal data shall be processed only for a specified purpose, in order to exercise a right or perform an obligation. This purpose shall be complied with in all phases of the data processing.

(2) No personal data shall be processed unless indispensable and suitable for the achievement of the purpose of the data processing, and only to the extent and for the duration necessary to achieve that purpose.

(3) Data processing based on compulsory supply of information may be ordered on grounds of public interest.

(4) Personal data may be processed – either with the data subject’s consent or when ordered by a rule of law – in particular where it is necessary for the performance of a task of public interest, for the data controller to perform his obligations prescribed by an Act, for the data controller or data recipient third person to perform their official duties, for the protection of the vital interests of the data subject, for the meeting of the obligations laid down in the contract between the data subject and the data controller, for the assertion of a legitimate interest of the data controller or a third person, or for the lawful operation of social organisations.

Article 32

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(2) Personal data shall be made anonymous as soon as the purpose of research allows it. Any data relating to identified or identifiable persons shall be stored separately from the very beginning. These data shall not be connected with other data unless this is required for the purpose of research.

Italy: Protection of individuals and other subjects with regard to the processing of personal data Act no. 675 of 31.12.1996 and New Data Protection code (Garante per la protezione dei dati personali)

including:

Section 3

(Data Minimisation Principle)

1. Information systems and software shall be configured by minimising the use of personal data and identification data, in such a way as to rule out their processing if the purposes sought in the individual cases can be achieved by using either anonymous data or suitable arrangements to allow

identifying data subjects only in cases of necessity, respectively.

Section 31

(Security Requirements)

1. Personal data undergoing processing shall be kept and controlled, also in consideration of technological innovations, of their nature and the specific features of the processing, in such a way as to minimise, by means of suitable preventative security measures, the risk of their destruction or loss, whether by accident or not, of unauthorized access to the data or of processing operations that are either unlawful or inconsistent with the purposes for which the data have been collected.

Section 78

(Information Provided by General Practitioners and Paediatricians)

1. General practitioners and paediatricians shall inform data subjects of the processing of personal data in a clear manner such as to allow the items referred to in Section 13(1) to be easily understandable.
 2. The information may be provided as regards the overall personal data processing operations that are required for prevention, diagnosis, treatment and rehabilitation as carried out by a general practitioner or a paediatrician to safeguard the data subject's health or bodily integrity, such activities being performed at the data subject's request or else being known to the data subject in that they are carried out in his/her interest.
 3. The information may also concern personal data collected from third parties and is given preferably in writing, also by means of pocketable cards with foldable annexes, and should include at least the items specified by the Garante in pursuance of Section 13(3), which may be supplemented by additional information – also verbally – in connection with specific features of the processing.
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4. Unless specified otherwise by the general practitioner or paediatrician, the information shall also concern data processing operations that are related to those carried out by said general practitioner or paediatrician, being performed by either a professional or another entity, who should be identifiable on the basis of the service requested and
 - a) temporarily replaces the general practitioner or paediatrician in question,
 - b) provides specialised advice at the general practitioner's or paediatrician's request,
 - c) may lawfully process the data within the framework of a professional partnership,
 - d) supplies prescribed drugs,
 - e) communicates personal data to the general practitioner or paediatrician in compliance with the applicable regulations.
 5. The information provided pursuant to this Section shall highlight, in detail, processing operations concerning personal data that may entail specific risks for the data subject's rights and fundamental

freedoms and dignity, in particular if the processing is carried out

a) for scientific purposes, including scientific research and controlled clinical drug testing, in compliance with laws and regulations, by especially pointing out that the consent, if necessary, is

given freely,

b) within the framework of tele-aid or tele-medicine services,

c) to supply other goods or services to the data subject via electronic communication networks.

Section 94

(Data Banks, Registers and Filing Systems in the Health Care Sector)

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Germany: Bundesdatenschutzgesetz and Landesdatenschutzgesetze

including:

§ 3 a BDSG: Minimisation Principle (Anonymisation, Pseudonymisation)

§ 4 a Abs. 3 BDSG: informed consent