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Legal and ethical framework for data distribution

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Executive Summary

Data sets for Benchmark 1 have been already provided, conditions of that provision have been covered in Deliverable *D2.1.1 Initial report on legal, ethical and privacy requirements for data distribution, focussing on Competition 1*. D2.1.1 covers mainly the data provision conditions for partners MUW and UKL-HD.

This document covers legal and ethical issues related to data disclosure for Benchmark 2. Part of the dataset will be provided by GENCAT, and accordingly this document covers specific requirements for this data transfer.

The VISCERAL project will create a centralised technological research infrastructure that will allow to benchmark retrieval and automated annotation of medical images. This infrastructure will include very large data sets of medical images on which to perform these operations.

These data sets will be created from patient health data collected as a result of clinical care. This information fulfils all the characteristics to be considered personal health data, which is a category of data particularly sensitive and for which European legislation offers therefore reinforced protection.

Considering the above, and previous to data disclosure, a detailed analysis has to be performed of legal issues related to the processing of personal health data and of ethical aspects of data disclosure for medical research.

Processing of personal data is regulated by the Data Protection Directive 95/46/EC. This Directive provides for a general prohibition of processing personal health information. Exemptions to this general prohibition are:

1. Processing of personal health data when informed consent from the patient exists
2. Processing of personal health data when there is a clear public interest

The VISCERAL project is not covered by either of these two exemptions and therefore original data will have to be de-identified prior to their transfer, as processing of anonymous data is not covered by the Directive.

As the VISCERAL project provides an organizational and technological infrastructure for medical imaging research projects to access imaging data in order to perform a benchmark, a clear workflow will have to be agreed between partners to govern:

1. Transfer of data to the storage infrastructure provided by VISCERAL
2. Subsequent access of every benchmark participant to that part of the dataset they need in order to perform the benchmark.

Contracts between all participants will have to be established in order to assure confidentiality, data security and compliance with data protection laws.

Another result of the project will be one or more than one data set of high quality, the product of manual annotations by radiologists and / or automated annotations obtained during the two benchmark processes. At the moment of writing this document, the nature of this derivative work and how to grant access to this final data set is not decided.

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1 Introduction

VISCERAL will make available to medical imaging research groups a collection of medical imaging datasets in digital format. Data sets for Benchmark 1 have been already provided, conditions of that provision have been covered in Deliverable *D2.1.1 Initial report on legal, ethical and privacy requirements for data distribution, focussing on Competition 1*. D2.1.1 covers the data provision conditions mainly for partners MUW and UKL-HD.

This document covers legal and ethical issues related to data disclosure for Benchmark 2. Part of the dataset will be provided by GENCAT, and accordingly this document covers specific requirements for this data transfer.

Original information consists of personal health data that has been collected within the context of medical care and is a subset of an electronic health record system.

Processing of patient data for the purposes of scientific research has to consider carefully the issues of data protection and privacy.

This document covers the general framework for data management policies within the project in order to reconcile project needs and legal requirements established in data protection laws.

It is important to notice that, while Data Protection Directive 95/46/EC dictates the common principles within the European Union, and therefore is used to extract the general rules that have to govern data management within the project, data processing will take place under the applicable national data protection rules that are a transposition of this Directive.

2 VISCERAL data sets

VISCERAL data sets will consist of medical images in digital format. This information has been originally obtained as a part of a clinical process, and comes into the category of personal health information.

This kind of information is considered to be highly sensitive, to the point that data protection laws forbid explicitly collection and processing of personal health data. The laws provide however some derogatory exemptions to this general prohibition:

1. Collection of personal health data is possible when a national law exists that allows it, which is a common situation within EU countries where national laws allow for personal health data to be collected in order to provide healthcare to individuals.
2. Processing of personal health data for research activities can be done either with consent of the person or when a clear public interest exists.

Data provided to VISCERAL will be a subset of different electronic health records provided by Agència de Qualitat i Avaluació Sanitàries (GENCAT). Information within these electronic health records have been collected in order to provide healthcare according to what is established in national laws, and the file has been declared to the data protection authorities as these laws specify.

With regard to data processing, it's not feasible to obtain informed consent from patients, nor can the VISCERAL project qualify for the exemption the laws foresee in the case of clear public interest.

Hence data will have to be de-identified prior to their transfer.

General considerations on how to achieve an anonymous data set, in the sense of what data protection laws account as anonymous, will be covered further in this document.

3 Legal background

There are different laws covering the different aspects of personal health data utilisation, from personal health data file creation to processing of this data for research activities.

3.1 Clinical records

A Spanish law and another (earlier) one passed by the Catalan Parliament on patients' autonomy have almost identical wording concerning the possibility of using clinical records for purposes of research.

> Spanish Parliament Law 41/2002, of 14 November, of Patient Autonomy [1]
>
> Article 16. Uses of the clinical record
>
> ...
>
> 3. Access to the clinical record for judicial, epidemiological, public health, research or educational purposes is governed by Organic Law 15/1999, of Personal Data, and Law 14/1986, General Health Law, and other rules that are applicable in each case. Access to the clinical record for such purposes carries an obligation to keep the patient's personal identification data separate from clinical and healthcare data, so that as a general rule anonymity is ensured, except when the patient himself or herself has given consent for them not to be separated ...

> Catalan Parliament Law 21/2000, of 29 December, on Patient Autonomy, the Right to Information and Clinical Documentation in Catalonia[2]
>
> Article 11. Uses of the clinical record
>
> ...
>
> 3. Access may be made to the clinical record for epidemiological, research or educational purposes, subject to the provisions of Organic Law 15/1999, of 13 December, of the Protection of Personal Data, and Spanish Law 14/1986, of 25 April, General Health Law, and associated provisions. Access to the clinical record for such purposes carries an obligation to keep the patient's personal identification data separate from clinical and healthcare data, except when the patient has given prior consent...
>
> Both laws allow then for the use of data from a patient's clinical records to be used for research purposes provided that this is done within the terms of the following laws:
>
> ☐ Organic Law for Data Protection (OLDP)
>
> ☐ General Health Law (GHL).

With regard to research, the GHL has been replaced by Law 14/2007 on Biomedical Research, which it will therefore also be necessary to review.

3.2 Data protection

As stated in the above laws regarding patient autonomy, the Organic Law for Data Protection establishes the terms under which personal information can be processed.

> Organic Law 15/1999, of 13 December, of the Protection of Personal Data. [3]
>
> Article 11. Communication of data.

> 1. Personal data can be communicated to a third party only for purposes directly related to the legitimate operations of the assignor and of the assignee with the prior consent of the person concerned.
>
> 2. The consent required in the foregoing section shall not be necessary:
>
> ...
>
> 6. If the communication takes place following a procedure of dissociation, the provisions of the foregoing sections shall not apply.

Furthermore, an Order of the Catalan Health Ministry declares the file to the Data Protection Authority together with its possible utilisations:

> Order SLT/519/2006, of 3 November, regulating files containing personal data in the Catalan Health Ministry. [4]
>
> [...It states the existence of a number of data files, including all the files of patients in public hospitals in Catalonia, in connection with which similar indications are made to the following...]
>
> Register of patients' health
>
> Purpose and intended uses
>
> ...
>
> The intended uses are to act as a necessary source of information for processes involving public health, health management and control, health planning, epidemiological studies, research and education, and for running statistical studies under article 17 of Law 23/1998, of 30 December, of Statistics in Catalonia. According to article 11.3 of Law 21/2000, of 29 December, on rights to health information and patient autonomy, and clinical documentation, use for epidemiological, research and educational purposes carries an obligation to keep the patient's personal identification data separate from clinical and healthcare data, except when the patient has given prior consent.
>
> ...
>
> Foreseen assignations of data
>
> To public authorities with health powers and to health professionals and scientific societies for activities connected with the purposes of the register, in accordance with Law 15/1990, of 9 July, of health management in Catalonia and Law 21/2000, of 29 December, on the right to health information and patient autonomy, and clinical documentation.

Thus, use in research and the assignment of data for that purpose is inherent in the creation of all data files that make up the Shared Clinical Records of Catalonia, including the imaging data base.

From the above article of the OLDP it is seen that:

- Data may only be assigned to comply with the legitimate purposes of the assignor and assignee.
- The assignation of data will normally require the consent of the interested party (the person being studied).
- These restrictions do not apply (from the point of view of the OLDP) if the data are previously disassociated, which is already required by the Laws quoted above with reference to uses of the Clinical Record.

4 Ethical requirements for medical research

Medical research is subject to deontological principles of the medical profession. Fulfilment of these requirements must be assessed at local level by each partner. As autonomy of the patient is a cornerstone of medical research, and informed consent a subject which can arise for some data sets within VISCERAL, some details are offered here.

4.1 Informed consent

The decision regarding the necessity of free informed consent procedures is dealt with by each partner, accordingly to the relevant legislation.

Free informed consent by participants in a medical study is a prime aspect of the ethical considerations concerning medical research. The Declaration of Helsinki states that "*The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.*", and "*After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing.*" (both: [5]). More detailed discussions are given in [6].

To fulfil the requirements of free informed consent, a participant has to have the right

- To know that participation is voluntary
- To ask questions and receive understandable answers before making a decision
- To know the degree of risk and burden involved in participation
- To know who will benefit from participation
- To know the procedures that will be implemented in the case of incidental findings
- To receive assurances that appropriate insurance cover is in place
- To withdraw themselves, their samples and data from the project at any time
- To know how their biological samples and data will be collected, protected during the project and destroyed at the end
- To know of any potential commercial exploitation of the research.

In the context of *retrospective studies* that use data acquired prior to study start, and where the collection of informed consent is not feasible or possible, benefits and risks have to be weighted by the competent Ethics Committee. There is a discussion regarding research on biological material in the context of bio banks in Tassé et al. [7]. The authors note: "*If it is not possible to recontact participants for reconsent, some guidelines allow for waived consent for the use of biological material, if certain conditions are met [8]. However, these conditions are not harmonized among international guidelines.*" The authors conclude further "*As stated in the Declaration of Helsinki, ethical principles apply to 'medical research involving human subjects, including research on identifiable human material or identifiable data'. It follows that research using anonymized or anonymous data does not create an obligation to obtain informed consent, as the study does not involve identifiable individuals*", taking [5] and [9] into account. In [9] the relevant paragraphs emphasize the role of the local competent Ethics Committee the decision of whether consent or re-consent is necessary if anonymized data is used:

- *"11. Under certain conditions, personal health information may be included on a database without consent, for example where this conforms with applicable national law that conforms to the requirements of this statement, or where ethical approval has been given by a specially*

appointed ethical review committee. In these exceptional cases, patients should be informed about the potential uses of their information, even if they have no right to object"

- *"14. Approval from a specially appointed ethical review committee must be obtained for all research using patient data, including for new research not envisaged at the time the data were collected. An important consideration for the committee in such cases will be whether patients should be contacted to obtain consent, or whether it is acceptable to use the information for the new purpose without returning to the patient for further consent. The committee's decisions must be in accordance with applicable national law and conform to the requirements of this statement."*

5 Data transfer to VISCERAL infrastructure

At the moment of writing this document formal procedure for data transfer has not been completely defined, but it will consist approximately of this workflow:

1. GENCAT will provide a list of available studies. This list is the result of a data extraction process aimed to classify imaging procedures by modality and anatomic region. Specifications of the data extraction process can be found in Deliverable *D.2.2.2 Data format definition focusing on Competition 2 and beyond*
2. The Consortium partner that will be responsible for the dataset will address a request to GENCAT, which will include at least:
    a. Identification of the organization and the applicant
    b. Amount of data requested for a given category
    c. Foreseen utilization of the data
    d. Scientific goals of the research
3. Once the request has obtained approval, data will be transferred to VISCERAL infrastructure
4. Research groups will sign an 'End User Agreement' with the Consortium partner responsible for the dataset

6 Data transfer agreements and contracts

Data transfer agreements and contracts will have to be signed between GENCAT, VISCERAL, and research groups accessing data sets.

Final documents are in process to be defined by GENCAT. They will take into account

- *CEN "Standard Form Contract to assist compliance with obligations imposed by article 17 of the Data Protection Directive 95/46"* [10]
- similar documents produced by other research projects

7 Organizational and technical security measures

Directive 95/46/EC does not include details on security measures. The reason for this absence is the continuous evolution of information technologies, and therefore leaves these measures to be decided according to existing technologies at the moment of implementing them.

Considering this absence of concrete measures, a standard generally accepted should be chosen in order to provide a baseline.

ISO's family 2700-X seems to fulfil the requirements to perform that role of establishing a baseline for technical security within the VISCERAL project. In particular "ISO/IEC 27001:2005 Information technology – Security techniques – Information security management systems" states a set of security controls and risk mitigation policies regarding the protection of information.

8 Data distribution during and after the benchmarks

All medical data are sensitive by nature and in the context of VISCERAL it will be assured that all data are only available for non-commercial research use and only after signature of a license agreement that assures the use of the data in its given environment and for its research purpose. In VISCERAL only registered participants can access the data and local copies of the data need to be destroyed after their use for research. The clauses of three ethics committees in Vienna, Barcelona and Heidelberg will be taken into account to assure that data treatment is in line with all ethical guidelines. In VISCERAL only anonymized data will be shared in any case and thus all necessary steps are taken into account to assure privacy.

The benchmarking campaign will be run in the cloud, in our case the cloud of Microsoft, also called Azure. Participants will obtain a virtual machine and access to a data source. All accesses to the virtual machines can be logged, as can accesses to the data. Only authorized persons will get access to the data and the large resource cannot easily be downloaded or reproduced locally, meaning that reuse can be controlled as well. Participants in the benchmark will also only have access to a small, manually controlled anonymous data set. Very small subsets can also be made available for download in connection with the license agreement to get used to the data format and image types. Clouds allow for storage of data in geographical regions such as in Europe. This allows making sure that local storage and access rules can be verified.

9 Conclusion

This deliverable describes the ethical, legal and privacy issues related to the data transfer by GENCAT to VISCERAL in order to fulfil Benchmark 2.

Since this data has been collected originally in order to provide health care, and medical research presents specific restrictions related to ethical aspects of the research, legal and ethical issues have to be properly addressed prior to data transfer.

Agència d'Avaluació, Informació i Qualitat has completed the high-level procedure for data request and transfer approval.

The detailed procedure is now in its last stage, including request form and legal contracts to be signed between GENCAT and the partner responsible for the dataset.

10 References

[1] http://www.boe.es/boe/dias/2002/11/15/pdfs/A40126-40132.pdf

[2] http://www.parlament.cat/activitat/cataleg/TL%2012Con.pdf

[3] http://www.agpd.es/portalwebAGPD/canaldocumentacion/legislacion/estatal/common/pdfs/Ley-15_99.pdf

[4] Declaration to the Data Protection Agency of Catalunya of the file "Registre d'informació sanitària de pacients" (Record of patient health information) (http://www.apd.cat/ca/registre_resultats_public.php?pag=30&registre[tipus_administracio]=2&registre[responsable]=Departament+de+Salut&registre[nif]=&registre[nom]=&registre[addr]=&registre[localitat]=&registre[cp]=&registre[provincia]=-1&registre[nom_fitxer]=&registre[finalitat]=&registre[tipus_diari]=-1&registre[butlleti]=&registre[data_pub]=&registre[lliure]=)

[5] WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects," Oct. 2008.

[6] European Textbook on Ethics in Research. pp. 1–212, Aug. 2010.

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