Big data analytics' and processing of health data for scientific research purposes : the Belgian legal framework

Research Protocol by Mahault Piéchaud Boura, for time.lex*)*
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1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

a. The legislative and regulatory instruments regulating the processing of health data for research purposes (current regime)

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.

The data Protection Act of 8 December 1992 (Loi relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel, 8 décembre 1992, publiée au Moniteur Belge du 18 Mars 1993) :

The Data Protection Act was the main legislation organisation the protection of personal data in Belgium. It was amended in 1998 to transpose *the Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereafter Directive 95/46/EC)*.

Royal Decree implementing the Data Protection Act of 8 December 1992 (hereafter the Royal Decree) (Arrêté royal portant exécution de la loi du 8 décembre 1992 relative à la protection de la vie privée à l'égard des traitements de données à caractère personnel) :

The Royal Decree implemented the Data Protection Act regarding the processing of special categories of data and data concerning health, in particular for the further processing of such data for scientific purposes.

Establishment and organisation of the eHealth Platform Act of 21 August 2008 (loi relative à l'institution et à l'organisation de la plate-forme eHealth et portant diverses dispositions/ wet houdende oprichting en organisatie van het eHealth-platform en diverse bepalingen) :

This act is relevant to the processing of data concerning health because it organises the access to electronic health records. It also institutes the Sectorial Committee of social security and health of the Privacy Commission, which is tasked to review the notification and associated requests of processing activities of data concerning health and social security.

Royale Decree of 3 May 1999 on general conditions for medical records (Arrêté royal déterminant les conditions générales minimales auxquelles le dossier médical/ Koninklijk besluit houdende bepaling van de algemene minimumvoorwaarden waarvan het medisch dossier).

Interesting resources: Vade-mecums of the privacy commission (now the Data Protection Authority)

- Vade-mecum for researchers: https://www.autoriteprotectiondonnees.be/node/3911 ;
- Vade-mecum for biomedical research: https://www.autoriteprotectiondonnees.be/node/3913 ;

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Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research.

Do shared electronic patient records exist in your country? How is the sharing of electronic patient records regulated? Can data stored in these records be used for research purposes?

Electronic health records exist in Belgium, however not in the form of a centralised institution setting up a "file" for each individual. Each patient has the right to a global medical file, as prescribed by the Royal Decree of 1999 on medical records. It is kept by a general practitioner. The global medical file is generally linked to an electronic version, to facilitate its transfer among health professional.[1] However, sharing of health data even among health professional is possible only with the informed consent of the patient.

Belgium's system organises a constellation of medical files through hubs set at different levels. This initiative has crystallised in 2008 with the adoption of the *Establishment and organisation of the eHealth Platform Act*. The eHealth platform does not administrate a general registry of medical records but provides services regarding the records and medical data in general. In particular there is a "Reference Directory".

The data held in the electronic medical file may be further processed for scientific research purpose, with the consent of the data subject. If the nature of research project does not allow for the information and subsequent collect of consent from the data subject, the authorisation of the Privacy Commission will be necessary for the research project to access the data necessary.

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework, introduced by the GDPR, addressed in your country? What is the adopted legislative approach?

In Belgium, the implementation of the *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* (hereafter the "GDPR") will require changes in the current legal framework. These changes will be implemented through different Acts.

- Loi portant création de l'Autorité de protection des données / Wet tot oprichting van de Gegevensbeschermingsautoriteit / Creation of the Data Protection Authority Act, 3 December 2017;

- Avant-projet de loi relatif à la protection des personnes physiques à l'égard des traitements de données à caractère personnel / Voorontwerp van wet betreffende de bescherming van natuurlijke personen ten opzichte van de verwerking van persoonsgegevens / Protection of natural persons with regard to the

[1] https://www.ordomedic.be/fr/avis/conseil/la-gestion-du-dossier-medical-global-%28dmg%29, last consulted the 21/03/2018

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processing of personal data Bill. The Bill was introduced to the Belgian lower chamber the 11 June 2018 and adopted the 19 July 2018, hereafter the New Data Protection Act (NDPA).[2]

Is the GDPR implemented in your country by an entirely new legislative text or via amendments to the current data protection law? Please explain.

The NDPA abrogates the Data Protection Act (1992) and the Royal Decrees implementing it.[3] Moreover, the NDPA aims to put Belgium law in conformity with the whole data protection Package, the GDPR as much as the Directive (EU) 2016/680 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data.

What are the main characteristics of the legislative implementation of the GDPR in your country?

The new framework was adopted in two steps. The first step is the Act creating the Data Protection Authority, which will replace the Privacy Commission (Commission de protection de la vie privée / Commissie voor de bescherming van de persoonlijke levensfeer). The second step is the adoption of the NDPA, which tackles substantives matters. The NDPA aims to implement the Regulation, where it left some leeway to the Member States.

- **What is your own assessment of the legislative approach adopted in your country for implementing the GDPR?**

Concerning the Title 4 organising the processing of personal data for scientific research purposes, the provisions seem to be mostly similar to the current regime organised by Royal Decree. The first draft was considered inadequate by the Privacy Commission in its opinion 33/2018 on the draft Bill.[4] The Commission considered that the safeguards proposes had such a low threshold of applicability it would hinder research. The Bill was redrafted accordingly.

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

The Privacy Commission was governed by the provisions set at Chapter VII of the Data Protection Act.

The Commission was composed of sixteen members, height permanents (including a President and Vice-President) and height substitutes, appointed for a renewable mandate of 6 years. The Commissioners were appointed by the

[2] http://www.dekamer.be/FLWB/PDF/54/3126/54K3126008.pdf, not yet formally enacted
[3] Data Protection Bill, Article 153.
[4] https://www.autoriteprotectiondonnees.be/sites/privacycommission/files/documents/avis_33_2018.pdf

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Chamber of Representatives among four categories: a legal expert, an IT expert and two individuals with experience in personal data management in the public and private sector, respectively.

The Commission had the competence to inform individuals, regardless of whether they are data subjects or controllers; ensure the right to access and rectify inaccurate data (indirect access); to record processing notifications filed by controllers; to keep the public register (of notifications); to handle complaints, which can imply providing information; to answer to questions asked by individuals and controllers. Moreover, the Commission reported to Parliament annually.

The Privacy Commission was subdivided in Sector Committees, which were competent to examine and decide on request for processing activities governed by specific legislations. The Sector Committee of Social Security and of Health, was competent to supervise the communication of data concerning health[5]. The Sector Committees ensured that the processing of personal data performed in various specific area do not infringe on privacy.

Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

The Privacy Commission will be replaced by a "Data Protection Authority" the 25 May 2018. The Data Protection Authority is established by the Creation of the Data Protection Authority Act, 3 December 2017.

The Data Protection Authority is composed of six different organs: the direction committee, the general secretariat, the first line service, the knowledge centre, the inspection service and the litigation chamber.

2. Transposition of Article 8.4 of Directive 95/46

Article 8 of Directive 95/46 prohibits, in principle, the processing of special categories of personal data concerning health. Article 8.2 lists a series of exceptions to this general prohibition. Article 8.4 states "*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*".

When transposing Directive 95/46 did your national legislator or supervisory authority make use of the power granted to Member States in Article 8.4 of the Directive? Did the legislator use this provision to insert any additional (i.e. additional to the exceptions listed in the Directive) exemption (to the prohibition to process health data) for the processing of health data for research purposes?

If yes, how is such an exemption formulated? Please explain.

The exemption could be found in Article 7 of the Data Protection Act but was organised in the Royal Decree from 2001. The Decree laid down rules regarding further processing, the conditions for processing of special categories of data, additional measures were required compared to processing of personal data.

[5] https://www.privacycommission.be/en/sc-h/competences-and-organisation

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Most importantly, the Decree set the principle that data further processed for scientific research purpose should be anonymised[6]. However, the Decree recognised that is not always possible given the nature of scientific research. If the purpose of the research project may not have been be fulfil with anonymised data, the "further controller" may have processed coded data.[7] Once again, the Decree recognised this may not have been sufficient to achieve the purposes of scientific research, given certain conditions, the controller may have processed non-coded data.[8]

a. Transposition of Article 8.4 of the Directive 95/46

What are the exceptions to the prohibition of processing sensitive data? Do any of these exceptions address scientific research in the field of health? How is such an exception formulated, and does it set out specific conditions?

The processing of special categories of data was organised by the Articles 6 (sensitive data) and 7 of the Act.

Article 7 dealt exclusively with data concerning health. The Article set the prohibition of processing as a principle and indicated eleven (11) possible exceptions. Article 7§2(j) for processing with purpose of preventive medicine or medical diagnosis, and Article 7§2(k) applicable for processing necessary for scientific research.

j) the processing is necessary for the purposes of preventive medicine or medical diagnosis, the provision of care or treatment to the data subject or to one of his relatives, or the management of health-care services in the interest of the data subject, and the data is processed under the supervision of a health professional;

k) the processing is required for the purposes of scientific research and carried out under the conditions established by the King by decree after deliberation in the Council of Ministers, having received the opinion of the Commission for the Protection of Privacy.[9]

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes? What is the scope? Which are the steps, and who are the key actors?

The processing for scientific research in governed by Article 7(2)(k). The specific conditions were laid down in the Royal Decree of 2001. However, this Decree made a clear distinction between the processing of personal data as set at Articles 6 and 7, and further processing for scientific research purpose.

[6] Royal decree, Article 3
[7] Royal decree, Article 4
[8] Royal decree, Article 5
[9] Data Protection Act of 1992, (translation), https://www.privacycommission.be/sites/privacycommission/files/documents/Privacy_Act_1992.pdf

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Any processing activity had to be notified to the Privacy Commission in application of the Article 17 of the Data Protection Act. The Privacy Commission had to send a receipt to the data controller within three days. This declaration had to contain certain elements.

- the name of the treatment;
- the purposes;
- the categories of data processed (and therefore not the data themselves);
- the possible legal or regulatory basis for the processing;
- the potential recipients to whom the data can be provided;
- guarantees in the event of communication to third parties;
- how data subjects are informed if their data are disclosed to third parties;
- the contact person to who you can address to exercise your rights;
- the measures taken to facilitate the exercise of the rights of the person concerned;
- the retention period;
- safety measures;
- the possible transfer abroad.

The declaration was registered by the Commission, who could ask for additional information as part of its control competence.

Processing of data concerning health was subjected to additional conditions compared to "simple" personal data. Article 25 of the Royal Decree list additional measures that data controller must take:

- The categories of person accessing the data had to be appointed by the data controller or his processor with a specific description of their functions in relation to the processing activity targeted;
- The list of persons thus appointed had to be kept at the disposal of the Privacy Commission.
- The appointed personnel had to be subject to a legal or statutory obligation of confidentiality, or an equivalent contractual obligation;
- When the data subject was informed, in application of Article 9(1) of the Act, the controller had to indicate the legal basis of the processing activity.

Moreover, the researchers had to prepare a security plan to use during the research project. This plan had to detail the technical infrastructure used, identify the personnel dealing with personal data, at which speed could data be coded and how could it be stored.

From which generally applicable data protection provisions are researchers exempted and under what conditions? For what reasons? From which provisions? What are the consequences?

Researchers may have been exempted of the obligation to inform data subjects set at Article 9 under specific conditions. According to Article 9(2) indent 2:

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The controller shall be exempted from providing the information referred to in this paragraph:

(a) where, in particular for processing for the purposes of statistics or historical or scientific research or for screening motivated by the protection and promotion of public health, it proves impossible or involves disproportionate efforts to inform the data subject;

(b) where the recording or communication of personal data is for the purpose of implementing a provision laid down by or pursuant to a law, decree or order.

The exemption was strictly limited to two situations. When the information of the data subjects turned out to be impossible or involved disproportionate efforts. Or when the processing was a legal obligation.

Article 31 of the Royal Decree provided further information about this exemption. Indeed, the data controller who could not inform the data subjects had to justify the impossibility to inform the data subject in the declaration made to the Privacy commission.

c. Are there additional specific conditions governing the processing of data for scientific research purposes?

What are the suitable safeguards applying to the exemption foreseen by Article 8.4 of the Directive in your country?

The processing of data concerning health for scientific purposes was organised by Article 7, it had to be done in compliance with the conditions set in the Royal Decree. Moreover the processing personnel had to be subject to a duty of confidentiality, and the processing activities had to be performed under the supervision of a health professional unless the data subject consented in writing (Article 7(4)).

Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

Article 7(4) provided that the processing of data concerning health may only have been carried out under the responsibility of the health professional. While this did not in its self-impose confidentiality, it was expected that the health professional would impose confidentiality to the processing personal either by way of contractual obligation, or by selecting personnel bound by confidentiality already.

Article 25 of the Royal Decree set out the conditions for the processing of special categories of data and health data, as seen above.

Are there specific requirements about the data subject's information? Or the person from whom the data was collected?

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Article 9 (1) of the Data Protection Act organised the information of the data subjects. The obligation to inform data subjects rested on the controller, it had to be performed at the latest when the data was obtained, so that the data subjects could have knowingly consented.

The controller had to provide his name and address, so that he could be reached, but also provide information on the purpose of the processing activity. The data subjects had to be informed of its rights such as the right to object to the processing, the right to access and ask for the rectification of inaccurate data. The controller also had to inform the data subject of the recipients of the data collected.

Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

Breach of the Data Protection Act provisions were sanctioned by Article 39 of the Act. Accordingly processing of health data in breach of Article 7 was punishable by a fine form one hundred to hundred thousand euro. The same was applicable to the breach of Article 4 or 17 of the Data Protection Act.

d. Formalities prior to processing: the general regime under the current framework

This section is relevant if the regime applying to processing for research in the field of health is a specific regime. But it may not always apply, and in such an instance the processing is ruled by the general regime.

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail? Where in the applicable legislation can it be found? What are this regime's main steps and conditions?

The processing must have been declared to the Privacy Commission in application of Article 17 of the Act. The declaration was added to the register of processing activities kept by the Privacy Commission.

3. Further processing of health data (for research purposes) : the current regime

How is the notion of further processing regulated in your national framework?

Further processing for scientific purposes was admissible if it was not incompatible with the initial purpose of collection of personal data. This principle set by the directive was transposed in the national law by Article 4(1), 2° of the Data Protection Act. However, the transposition set conditions. The further processing had to comply with

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the condition of processing set by the Royal decree. The Data Protection Act also required appropriate guarantees for the storage of personal data for scientific research purposes. This was an exception to the principle of purpose limitation set by Article 4(1), 5°, first sentence. The guarantees were also organised by the Royale Decree.

The Royal Decree recalled the presumption of compatibility of further processing for scientific purpose in its Article 2.

Article 7 of the Data Protection Act sets the principle according to which data concerning health may only be collected from data subjects, unless the collect complies with the guarantees set by the Royal Decree, and be done by a health professional, or someone subject to an equivalent duty of confidentiality. Moreover, the collect from other sources must be necessary for the purpose of the research or data subjects must not be able to provide the data themselves.

Are there specific conditions for further processing for scientific research in the field of health purposes?

Conditions regarding further processing for scientific purpose were governed by the Royal Decree.

The Royal Decree was organised in different sections, depending on the degree of identification possible of data subjects necessary for the research. The Vade-mecum of the Privacy Commission on processing of personal data for scientific research purpose, indicates clearly that researchers should as a starting point of their research determine the degree of identifiability of the data necessary for the research. The Decree catered for three options: anonymous, coded and non-coded.

As a general principle the Royal Decree indicated the further processing for scientific research purpose was done with anonymised data (Article 3). However, if processing anonymised data did not enable the research project to fulfil its purposes, the researcher may have processed coded personal data (Article 4). This must have been justified in the declaration of the processing done to the Privacy Commission in application of Article 17 of the Act. Nevertheless, if the processing of coded personal data still did not enable the research project to achieve its purposes, the controller of the further processing activity could use non-coded personal data. As before, this must have been justified in the declaration of the processing done to the Privacy Commission in application of Article 17 of the Act.

When the research project required the use of coded data, two situations were possible:

- Either researchers used data collected for another purpose, in this case, the data must have been coded prior to its further processing, by the researchers (controller) or the entity tasked with the processing (the processor) (Article 8 Royale Decree);
- Or the researchers collected data from other sources, in the case the data was transferred coded to researchers by the initial controller or an intermediary entity (Article 9). Moreover, before receiving personal data, the researchers must have justified of a receipt of the processing declaration delivered by the Privacy Commission (Article 17 §2) to the initial controller who was transferring the data.

The coding of the personal data had to be done according to protocols ensuring the coded data could not be converted back into non-coded data (Article 12 Royale Decree) by the initial controller prior to the transfer/ communication.

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When the controller wished to code personal data without informing the data subjects, the Privacy Commission had to be informed, through the declaration of the processing activity specific to the scientific purposes of the processing, the reason(s) for processing non-coded data, the justification for not informing the data subjects, the persons or categories of persons with access to the processed data and the origin of the data. The Privacy Commission, within forty-five days informed of its recommendations and possible additional conditions to comply with (Article 16).

When the research project required the use of non-coded data, two situations were possible:

- Researchers had to obtain the explicit consent of the data subject prior to the further processing (Article 19 of the Royal Decree).

- Researchers had to further process personal data for scientific research purpose without informing and obtaining the explicit consent of the data subject, if the Privacy Commission was appropriately informed. Researchers had to communicate in the declaration: specific of the scientific purposes of the processing, the reason(s) for processing non-coded data, the justification for not informing the data subject and not obtaining their consent, the persons or categories of persons with access to the processed data and the origin of the data. The Privacy Commission, within forty-five days informed of its recommendations and possible additional conditions to comply with (Article 21 of the Royal Decree).

The authorisation of the Sector Committee social security and health, the section within the Privacy Commission competent to assess these requests was required in certain specific situations, where the processing was considered as primary processing by the applicable legislation. Research project collecting data for further processing from the social security sector or the health sector must have been authorised to do so by the competent section of the Social security and Health Sector Committee.

The request for an authorisation was done in writing to the Committee, there was no specific form to respect, however the request must have described in a very clear manner which personal data relating to which data subject would be communicated by who to which recipients and for which purposes. To that end the request had to at least provide the identity and the mission of all personnel concerned by the processing of personal data, the purposes targeted by the processing, a clear description of the data flows, the duration of the data retention period and a description of the security measures to be implemented regarding the data.

The authorisation of the Committee could only cover the data listed in the request, researchers had to carefully envisage the data necessary for their project.

What are the rights of the data subject when it comes to such further processing?

According to Article 9(2) of the Data Protection Act, in the situation of further processing data subjects had to be informed of the name and address of the controller, of the purpose of the processing and of the right to oppose such processing. The information was provided by the controller upon registering the data collected, or when the data was to be transferred at the latest when the data was transferred. Moreover, unless it was not necessary to unsure the fairness of the processing, the data subjects were given additional information on the categories of data processed, the recipients or categories of recipients of the data and on their right to access and rectify their data.

The Royal Decree provided additional rules concerning the information of the data subjects and their rights, taking in account whether the data was coded or not.

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Coded data:

The data subjects were informed by the initial controller of the coding of its personal data concerning health and received information concerning the identity of the data controller, the categories of personal data processed, the origin of the data, a specific description of the processing purposes, the recipients or categories or recipients of the data, the existence of a right to access and rectify the data, and of their right to oppose the further processing.

Non-coded data:

The 'further controller' prior to the further processing informed data subjects of the identity of the data controller, the categories of personal data processed, the origin of the data, a specific description of the processing purposes, the recipients or categories of recipient of the data, the existence of a right to access and rectify the data, and the controller's obligation to obtain their consent (Article 18 Royal Decree).

- **What about the data subject's rights and further processing for scientific research purposes?**

It follows from the previous section that data subjects had the right to object to the processing of the personal data for scientific purposes, they also had the rights to access the data processed and have it rectified it is inaccurate. However, under certain circumstances, these rights may not have been available to them. In application of Article 28 of the Royal Decree, the controller of a processing activity using only coded data was exempted of the obligation to inform data subjects, if the processing complied with the provisions of the Royal Decree governing the further processing of coded personal data for scientific research purpose.

Indeed, when controllers were exempted of the obligation to inform the data subject, de facto the right to access and rectify the data processed were not applicable.

4. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

Under the GDPR the processing of health data for research purposes is regulated by Article 9(2)(j), which authorises the processing of health data if this "*processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)* ***based on Union or Member State law*** *which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject*" (emphasis added), and is combined with Article 89(1) ("*Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner")*.

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a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

Protection of natural persons with regard to the processing of personal data Bill (the Data Protection Bill) is organised in different titles. Title 4 deals with processing for archives of public interest purpose, scientific or historic research purpose or statistical purposes.

The approach taken by the Belgian legislator is the following: at the inception of a project research are to determine whether the aim of the research can be achieved complying with the GDPR and respecting the rights of data subjects. Depending on the answer either the GDPR regime will apply, without any specific derogation, or the regime set in the NDPA will.[10] In this case there are two options either following the obligation of a register and DPO or the adhesion to a Code of Conduct.[11]

The regime set by the NDPA sets the safeguards required for the implementation of Article 89(2) of the GDPR. The rights mentioned in this Article may be derogated to if their exercise were to render impossible or seriously impair processing for scientific research purposes. This regime must be complied with, unless the controllers adheres to a code of conduct approved by a supervisory authority. Moreover, like in the former framework, the use of anonymised data is to be preferred over pseudonymised data. However, if the use of anonymised data is not possible or practical, pseudonymised data, or even non-pseudonymised, data may be used.[12]

First, if the processing is likely to result in high risks for the rights and freedoms of data subjects,[13] a data protection officer must be appointed.[14] The threshold for the appointment is lower than the one set by the GDPR.[15] Second, the NDPA adds some fields to the data processing records. The justification for the use pseudonymised or identifying data, the grounds for the derogation to data subjects' rights and the results of the DPIA when special categories of data are processed.

The regime set by the NDPA makes the distinction between data collected directly form the data subject and data re-used for scientific purposes.

In the case of direct collect from data subjects, they are informed whether that data will be anonymised or not, and the grounds on which some of their rights are not applicable.[16] Data thus collected are anonymised or pseudonymised after they are collected,[17] or before they are further processed by the same controller.[18] De-pseudonymisation is only possible if it is necessary for scientific research purposes and after the opinion of the DPO[19]. If the data are transferred to a distinct controller, for further processing (further controller), data are

[10] CHAMBRE 5 e SESSION DE LA 54 e LÉGISLATURE, DOC 54 3126/007 (http://www.lachambre.be/FLWB/PDF/54/3126/54K3126007.pdf)
[11] Article 187, NDPA (doc 3126/007)
[12] Article 197 NDPA
[13] Article 35 GDPR
[14] Article 190, NDPA
[15] Article 37 GDPR
[16] Article 193 NDPA
[17] Article 198 NDPA
[18] Article 199 NDPA
[19] Article 200 NDPA

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pseudonymised by the initial controller, who keeps the pseudonymisation key.[20] The DPO, if one was appointed gives advice on the pseudonymisation[21] process or method.

In the case of re-use of data a convention between the initial controller and the further controller must be concluded.[22] This convention must indicate the contact details of both the initial and the further controller and the grounds for which data subject rights may be derogated to.[23] This convention is annexed to the records.[24] Data communicated to the further controller is pseudonymised by the initial controller, who keeps the pseudonymisation key.[25] Data communicated for further processing for scientific research purposes may not be reproduced if they are data from a special category of data, if it is prohibited by the data sharing convention between the initial and further controllers.[26]

Additionally, when processing health, genetic or biometric data, controller are expected to implement specific safeguards. The personnel tasked with the processing of such data must be appointed by the controller (or processor) with a specific description of their allotted tasks. Additionally, the personnel must be bound by a legal or statutory obligation of confidentiality. A list the appointed personnel is kept at the disposal of the Data Protection Authority (Article 9 NDPA)

b. Modification to the processing authorisation procedure applying to research in the field of health

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change? Is it a logical change? Is the supervisory authority involved? If yes, how?

The NDPA does not provide for an authorisation procedure. However, a combined reading of the Bill and the GDPR shows that the mechanisms may *de facto* amount to an authorisation procedure.

In application of Article 35 (3)(c) of the GDPR the Data Protection impact assessment will have to be performed, because research amounts to processing in a large scale of special categories of data.[27] Depending on the result of the DPIA, the Data Protection Authority may have to be notified. In application of Article 36 of the GDPR, if the DPIA indicates the processing would result in a high risk for the for the rights and freedoms of data subjects without the implementation of appropriate mitigating measures by the controller, the Data Protection Authority must be notified. If the authority deems it necessary, the controller will be provided with advices and/or the Data Protection Authority may use its powers as laid down in Article 58 of the GDPR.

Moreover, with the implementation of the GDPR all controls performed by the Data Protection Authority intervene after the processing activity started. In the event of such control, the Data Protection Authority is entitled to access

[20] Article 201 NDPA
[21] Article 204 NDPA
[22] Article 194 NDPA
[23] Article 195 NDPA
[24] Article 196 NDPA
[25] Article 201 NDPA
[26] Article 207 NDPA
[27] Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679, WP 248 rev.01, pp. 9-10

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any documents pertaining to the processing. This control will be as much about the means of processing that the means of collect of data.

What about the right of the data subject and the obligations of the controller?

Data subjects must be informed by the researchers, in application of the relevant GDPR provisions. However, the right of access and rectification are not applicable when they would seriously impair or render impossible the purpose of the research project. This must be justified by the controller and his DPO, and these justifications must be indicated in the register (Article 191 NDPA). The same obligation applies to the results of the DPIA.

In Article 186 of the NDPA the legislator takes the opportunity given by the GDPR in Article 89(2). The rights laid down in Articles 15 (rights of access), 16 (right to rectification), 18 (rights to restriction of processing) and 21 (right to object) GDPR may be derogated to by law of the Member States. Article 186 NDPA provides exemptions to Article 15 (rights of access), Article 18 (right to restriction of processing) and 21 (right to object), if a recognised Code of Conduct or if the regime set in the NDPA is complied with.

5. Further processing for research purposes under the GDPR

Further processing of personal data for scientific research purposes is regulated in the GDPR by Article 5(1)(b) ("*further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes*") and Article 89(1) ("*Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner*").

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

The NDPA requires that the transfer from the initial data controller and the researcher have an agreement organising the communication of data[28]. The agreement must contain a certain number of provisions, such as the contact details of both data controller 'initial' and 'further', and the grounds on which data subjects' rights to access , restriction and object to the processing may be derogated to.

The convention must be annexed to the records of processing activities maintained by the further controller.

In certain circumstances the obligation to conclude a data sharing agreement may be derogated to. However in such cases, the further controller must inform the initial controller of the re-use of data.[29] This happens when the data

[28] Article 194 NDPA
[29] Article 194 NDPA

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used is public data or when existing legislations, national or European mandate the controller for the processing for scientific purpose or prohibits the use of data for other purposes.

The possible derogation to data subjects' rights are the same than for primary processing.

6. Health data sources for research purposes

This section seeks to identify information on the availability of health data for research purposes. Do public authorities or other entities facilitate the availability of health data for research purposes? In what way? Under what conditions?

a. Sources of data and their regulation

What are the different sources of health data that can be used for research purposes?

Direct collect, communication of existing data sets from public data bases, health data for eHealth platform, social security data from "Banque carrefour de la sécurité sociale"/ "Kruispuntbank van de sociale zekerheid", Crossroad Bank for social security are the main sources of health data for scientific research purposes.

- **DIRECT COLLECTION FROM THE PATIENTS:**

Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

Despite the fact that applicable legislation considered further processing as the favoured method of data collect for scientific research purpose, the Privacy Commission recognised in the Vade-mecum drafted for researchers that often research projects actually require their own collect of data.

The collect of data had to comply with the applicable legislation. It had to comply with the principle of quality of processing as laid down in Article 4 of the Data Protection Act with the informed consent of data subjects (Article 7(2)(a)), this implied that data subjects were informed in application of the Article 9 (1) of the Data Protection Act. The processing activity had to be declared to the Privacy Commission, in application of Article 17 of the Act.

In application of Article 25 of the Royal decree, additional conditions had to be complied with. The list of persons who would process the data must have been drawn up precisely and include their skills and function. This list had to be kept available to the Commission and such persons must have been bound by a contractual or statutory obligation of confidentiality. The information must also have indicated which legal base justified the processing of this type of data.

On principle data should have been anonymised or pseudonymised prior to the processing. If not, this had to be indicated in the declaration.

The processing of social security data collected from the "cross road bank for social security" and the national register were considered by the law as primary/ initial purpose of processing.

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The "cross road bank for social security" compiles data set for research purposes, in application of the Article 5 of "cross road bank for social security Act".[30]

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Similarly, to the current framework, the revised framework favours the further processing due to the GDPR provisions. But the new regime applicable to the collect of data for scientific research purposes is set in the Act in Articles 193 to 206.

The obligation to declare a processing operation is replaced by the obligation for the controller to appoint a Data Protection Officer when the processing is likely to result in high risks for the rights and freedoms of data subjects and to keep a register of the processing activities, to be kept at the disposal of the Data Protection Authority.

The data processed for scientific purposes should be anonymised data, and if this is not possible the use of pseudonymised data or even non pseudonymised data should be justified by the controller and annexed to the register (Article 197 NDPA).

Data subjects must be informed and give their consent, in application of the relevant provisions of the GDPR, and the DPO must give its opinion on the information provided, this should be annexed to the register.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for data subjects, in the absence of adoption of mitigating measure by the data controller, the Data Protection Authority will have to be consulted (Article 36 GDPR).

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS:**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

The collection of data concerning health through health professional or health institution was considered further processing. As such it was governed by Article 7 (5) second indent of the Data Protection Act. This was effectively organised by the Royal decree. In principle further processing should have been performed with anonymised data, and if this was not possible the use of pseudonymised data or even non pseudonymised data should have been justified in the declaration of processing activity. Either way the data necessary for the purpose, and their level of encryption should have been determined at the onset by the controller.

The processing activity had to be declared to the Privacy Commission, in application of Article 17 of the Act, the Sector committee on social security and health could issue recommendations, when the data subject could not be informed of the further processing, in application of Article 16 or 19 of the Royal Decree. In any case the Privacy

[30] http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1990011531&table_name=loi

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Commission provided a receipt of the declaration to the controller. This receipt would be required by the initial controller prior to the communication of the data to the 'further' controller.

The data had be coded/pseudonymised before being communicated to the 'further' controller, this was the responsibility of the controller initial.

Data subjects must have given their informed consent to the transfer and coding of their health data and have been informed in application of the Article 14 of the Royale decree. If the information could not be communicated to the data subject, additional information and justification had to be provided to the Privacy Commission (Sector committee for social security and health), in application of Article 16 of the Royal decree. The Commission would then provide recommendation to the 'further' controller on the course of action.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Under the revised framework, the processing activity does not need to be declared to the Data Protection Authority, however the further controller must appoint a Data Protection Officer (if necessary in application of Article 197 NDPA) and keep a register of the processing activities to be left at the disposal of the Data Protection Authority. All the opinions and justification of the decision of the controller about the conduct of the processing operation should be annexed to the Register.

The communication of data should be organised by an agreement containing the information indicated in the Article 194 NDPA, which then must be reviewed by the Data Protection Officer.

Data subjects must be informed in application of the relevant provision of the GDPR and be aware of the rights under the Regulation. However, according to Article 186 NDPA, the right to access and the right to have inaccurate data rectified do not apply when they may render impossible or seriously impair the fulfilment of the purposes of the research project.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for the data subject, in the absence of adoption of mitigating measure by the data controller, the data protection will have to be consulted (Article 36 GDPR).

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

Collect of data from private data base had to be the object of a communication agreement between the data holder and the researchers, which are the 'further' controller. As such it was governed by Article 7 (5) second indent of the Act. This was effectively organised by the Royal Decree. In principle further processing should have been performed with anonymised data, and if this was not possible the use of pseudonymised data or even non-pseudonymised data should have been justified in the declaration of processing activity. Either way the data necessary for the purposes, and their level of encryption should have been determined at the onset by the controller.

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The processing activity must have been declared to the Privacy Commission, in application of Article 17 of the Act, the Sector committee on social security and health could issue recommendations, when data subjects could not be informed of the further processing, in application of Articles 16 or 19 of the Royal Decree. In any case the Privacy Commission provided a receipt of the declaration to the controller. This receipt would be required by the initial controller prior to the communication of the data to the 'further' controller.

The data had to be coded/pseudonymised before it is communicated to the 'further' controller, this was the responsibility of the controller initial.

Data subjects must have given their informed consent to the communication and coding of their health data and have been informed in application of the Article 14 of the Royale decree. If the information could not be communicated to data subjects, additional information and justification must have been provided to the Privacy Commission (Sector committee for social security and health), in application of Article 16 of the Royal decree. The Commission would then provide recommendation to the further controller on the course of action.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Under the revised framework, the processing activity is not declared to the Data Protection Authority, however the further controller may have to appoint a Data Protection Officer and keep a register of the processing activities to be left at the disposal of the Data Protection Authority.

The communication of data should be organised by an agreement, which then must be reviewed by the Data Protection Officer.

The data subject must be informed in application of the relevant provision of the GDPR and be aware of the rights under the Regulation. However, the right to access and the right to have inaccurate data rectified do not apply when they may render impossible or seriously impair the fulfilment of the purposes of the research project or when applicable legislation.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for the data subject, in the absence of adoption of mitigating measure by the data controller, the data protection will have to be consulted (Article 36 GDPR).

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

In Belgium, the public data base organising health data have a common repository in the e-Health platform. The access was granted by the platform on a motivated application of the further controller after the authorisation of the CSSS of the Privacy Commission.[31]

As such it was governed by Article 7 (5) second indent of the Act. This was effectively organised by the Royal Decree. In principle further processing should have been performed with anonymised data, and if this was not possible the use of pseudonymised data or even non pseudonymised data should have been justified in the declaration of

[31] Article 5, 8° of the institution and organisation of the e-Health Platform Act of 21 August 2008

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processing activity. Either way the data necessary for the purposes, and their level of encryption should have been determined at the onset by the controller.

The processing activity must have been declared to the Privacy Commission, in application of Article 17 of the Act, the Sector committee on social security and health could issue recommendations, when the data subject could not be informed of the further processing. In any case the Privacy Commission provided a receipt of the declaration to the controller. This receipt would be required by the initial controller prior to the communication of the data to the further controller.

The data must have been coded by the e-Health Platform before it is communicated to the 'further' controller, this was the responsibility of the controller initial. The use of non-coded data must have been justified to the Privacy Commission and approved in the recommendation given.

The data subjects must have given their informed consent to the transfer and coding of its health data and have been informed in application of the Article 14 of the Royale decree. If the information could not be communicated to the data subject, additional information and justification must have been provided to the Privacy Commission (Sector committee for social security and health), in application of Article 16 of the Royal decree. The Commission would provide recommendation to the 'further' controller on the course of action.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The 'further' controller may have to appoint a data protection officer and must keep a register of the processing activities to be left at the disposal of the Data protection authority.

The communication of data should be organised by an agreement containing the clauses indicated in the Article 194 NDPA, which then must be reviewed by the Data Protection Officer.

The data subject must be informed in application of the relevant provision of the GDPR, on be aware of the rights under the Regulation. However, the right to access and the right to have inaccurate data rectified do not apply when they may render the impossible or seriously impair the fulfilment of the purposes of the research project and the research projects comply with a recognised code of conduct or of the regime set in the NDPA.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for the data subject, in the absence of adoption of mitigating measure by the data controller, the data protection will have to be consulted (Article 36 GDPR).

b. The application of the national framework to the AEGLE cases

This section seeks a short summary of the rules to be observed in your country by a hypothetical researcher involved in the AEGLE project. The objective is to obtain a practical response for informing such a researcher as clearly as possible.

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1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, health data collected from patients who have expressed their consent with their data being used further for research purposes.

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body? Should the patient be informed about the new research project? Is a new patient consent, specifically focusing on the precise research project, required?

Researchers using the AEGLE Platform in Belgium would have to establish a clear list of the categories of data needed for their research as well as the sources of these data. If the data would have been obtained from public sources, such as public data bases accessible through the e-Health platform, the procedure may have varied somewhat.

The researchers would have to have declared the processing to the Privacy Commission, in application of the Article 17 of the Data Protection Act. However, the processing would have been done under the authority of a health professional, according to Article 7(4) of the Data Protection Act, unless data subjects had expressly consented otherwise. And the personnel processing the data would be subject to a duty of confidentiality. Moreover, the researchers would have complied with additional the conditions set by Article 25 of the Royal Decree, the categories of persons processing the data would have been appointed by the controller of its processor with a clear description of their task, this would have been compiled in a list left at the disposal of the Privacy Commission. The person processing the personal data would have been bound by a duty of confidentiality. Moreover, the information communicated to data subjects prior to the processing would have contain the legal ground justify the processing.

The data subjects would have had to be informed prior to the data communication by the initial processor of the identity of the further controller (that is the researcher), of the categories of data concerned by the transfer, of the origin of the data, of a specific purpose of the processing, of the recipients of the data, of their right to access the data and have inaccurate data rectified and of their right to oppose the transfer, coding and further processing.

The data would have communicated to the researcher already coded/pseudonymised by the 'initial' data controller, and the 'further' processor would not have been able to decode the data, upon presentation by the 'further' processor of the notification of processing receipt given by the Privacy Commission.

In the situation where the research would have obtained data through the e-Health platform, the researcher would have had to apply to the e-Health platform to have access to the data, or the social security crossroad bank to obtain social security data. The data would have been communicated upon demonstration of the receipt given by the Privacy Commission after the notification of the processing activities (in application of Article 17 of the Data Protection Act).

Revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

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Under the revised framework the researchers, or the sponsor organisation of the researchers, may have to appoint a Data Protection Officer to ensure the compliance with the applicable data protection legislation. Moreover, researchers must keep a register of the processing activities performed for the purpose of the research. The researchers will have the obligation to annex to this register all the opinions of the DPO and the justifications of the course of action taken for the processing of personal data.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for the data subject, in the absence of adoption of mitigating measure by the data controller, the data protection will have to be consulted (Article 36 GDPR).

The communication of data from the initial controller must be organised by a data communication agreement, in application of Article 194 NDPA.

2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other type of approval required? From which body? Should the patient be informed about the new research project?

The researchers would have to have declared the processing to the Privacy Commission, in application of the Article 17 of the Data Protection Act. However, the processing would have been done under the authority of a health professional, according to Article 7(4) of the Data Protection Act, unless data subjects had expressly consented otherwise. And the personnel processing the data would be subject to a duty of confidentiality. Moreover, the researchers would have complied with the additional conditions set by Article 25 of the Royal Decree, the categories of persons processing the data would have been appointed by the controller of its processor with a clear description of their task, this would have been compiled in a list left at the disposal of the Privacy Commission. The person processing the personal data would have been bound by a duty of confidentiality. Moreover, the information communicated to the data subject prior to the processing would have contain the legal ground justify the processing.

Data are collected through ICU devices without the consent of data subjects. It could have been further processed for scientific research purposes because it is considered compatible with the initial purpose in application of the Article 4(1)2° of the Act, and Article 2 of the Royal Decree, the legal base for the processing is Article 7(2)(k) of the Act.

Data subjects would have been informed prior to the data communication by the initial controller of the identity of the 'further' controller (that is the researcher), of the categories of data concerned by the transfer, of the origin of the data, of the specific purposes of the processing, of the recipients of the data, of their right to access the data and have inaccurate data rectified and of their right to oppose the transfer, coding and further processing.

However, if the information of the data subject had been impossible or required unreasonable efforts, this obligation could be derogated to, in application of Article 15 and 16 of the Royal Decree. In that case additional information would be given to the Privacy Commission, who would issue recommendation on the course of action within 45

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days. However, if the Commission did not issue a recommendation within this time frame, the application for further processing or coding without the information of the data subject would be considered as accepted.

The data would be communicated to the researcher already coded/pseudonymised by the initial data controller, and the further processor would not be able to decode the data, upon presentation by the further processor of the notification of the processing receipt delivered by the Privacy Commission.

Revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Under the revised framework researchers, or their sponsor organisation, must appoint a Data Protection Officer to ensure the compliance with the applicable data protection legislation. Moreover, the research must keep a register of the processing activities performed for the purpose of the research. Researchers will have the obligation to annex to this register all the opinion of the Data Protection Officer and the justification of the course of action taken for the processing of personal data.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for the data subject, in the absence of adoption of mitigating measure by the data controller, the data protection will have to be consulted (Article 36 GDPR).

The communication of data from the initial controller, here probably a health institution, must be organised by a communication agreement, in application Article 194 NDPA. It is the responsibility of the initial controller to pseudonymise the data prior to the communication to the 'further' controller, who does not have access to the pseudonymisation key, Article 199 NDPA.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body? Should the patient be informed about the new research project?

The researchers would have to have declared the processing to the Privacy Commission, in application of the Article 17 of the Data Protection Act. However, the processing would have been done under the authority of a health professional, according to Article 7(4) of the Data Protection Act, unless data subjects had expressly consented otherwise. And the personnel processing the data would be subject to a duty of confidentiality. Moreover, the researchers would have complied with additional the conditions set by Article 25 of the Royal Decree, the categories of persons processing the data would have been appointed by the controller of its processor with a clear description of their task, this would have been compiled in a list left at the disposal of the Privacy Commission. The person

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processing the personal data would have been bound by a duty of confidentiality. Moreover, the information communicated to the data subject prior to the processing would have contain the legal ground justify the processing.

Data subjects would be informed prior to the data communication by the initial processor of the identity of the further controller (that is the researcher), of the categories of data concerned by the communication, of the origin of the data, of a specific purpose of the processing, of the recipients of the data, of their right to access the data and have inaccurate data rectified and of their right to oppose the transfer, coding and further processing. However, this is the hypotheses of a biobank, so data subjects must have been informed upon the collect of their data, of a possible further processing and of the possible coding of their data.

However, if the information of the data subject had been impossible or required unreasonable efforts, this obligation would be derogated to, in application of Articles 15 and 16 of the Royal Decree. In that case additional information would be given to the Privacy Commission, who would issue recommendation on the course of action within 45 days. However, if the Commission did not issue a recommendation within this time frame, the application for further processing or coding without the information of the data subject could be considered as accepted.

The data would be communicated to the researcher already coded/pseudonymised by the initial data controller, and the further processor would not be able to decode the data, upon presentation by the further processor of the notification of processing receipt given by the Privacy Commission.

Revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Under the revised framework the researchers, or the sponsor organisation of the researcher, may have to appoint a Data Protection Officer to ensure the compliance with the applicable data protection legislation. Moreover, researchers must keep a register of the processing activities performed for the purpose of the research. The researchers will have the obligation to annex to this register all the opinion of the Data Protection Officer and the justification of the course of action taken for the processing of personal data.

A Data Protection Impact Assessment must be performed, in application of Article 35(3)(b). If the outcome shows high risks for the data subject, in the absence of adoption of mitigating measure by the data controller, the data protection will have to be consulted (Article 36 GDPR).

The communication of data from the initial controller, here probably a health institution, must be organised by a communication agreement. It is the responsibility of the initial controller to pseudonymise the data prior to the communication to the further controller, who does not have access to the pseudonymisation key.

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