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

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1. Overview of the legal framework

a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018)

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.

(A) The General Data Protection, Regulation (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, and repealing Directive 95/46/EC ("**GDPR**"). The GDPR entered into force on 25th May 2018 and is the relevant legislation governing data protection in Malta, having direct effect across all European Union Member States. The Data Protection Act (Chapter 586 of the Laws of Malta) (the "**DPA**") and subsidiary legislation promulgated thereunder serves to specify certain issues which are left to Member State law to regulate. The GDPR provides that health data is considered to fall within a special category of data which is subject to additional safeguards and the legal grounds for processing are restricted to those established in Article 9 of the GDPR. Article 9(2)(j) of the GDPR provides that processing 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. In turn, Article 89(1) of the GDPR provides processing for archiving purposes in the public interest, scientific or historical research purposes of 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 order to ensure respect for the principle of data minimisation. Those measures may include pseudonymimsation provided that those purposes can be fulfilled in that manner. Where those purposes can by fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in such a manner. Therefore, pursuant to the above, the processing of health data for scientific research purposes is considered to be lawful. However, such processing must be subject to appropriate safeguards for the rights and freedoms of data subjects.

(B) The DPA repealed the previous Data Protection Act and transposed the provisions of GDPR in their entirety into Maltese law. As such, the provisions of the GDPR shall be the main focus of this work, however, in certain cases, the GDPR does provide for Union or Member State law to provide for derogations in certain instances, including as regards processing for research purposes. As a result, the relevant provisions of the DPA shall also be examined. In particular, Article 7 of the DPA provides that a data controller shall consult with, and obtain prior authorisation from, the Information and Data Protection Commissioner where the controller intends to process genetic data, biometric data or data concerning health for statistical or research purposes and in cases where such data are required to be processed for research purposes, the Information and Data Protection Commissioner shall consult a research ethics committee or an institution which has been duly recognised. . However, such processing carried out for research purposes can only be carried out if approved by the Information and Data Protection Commissioner, upon the advice of the its advisory body.

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(C) The Health Act, Chapter 528 of the Laws of Malta (the "**HA**") also regulates processing of health data given that it provides grants patients the right to have their data processed in conformity with the Act and also regulates the following:

(D) The Processing of Data Concerning Health For Insurance Purposes Regulations (Subsidiary Legislation 586.10) also regulates the processing of health data within the context of insurance matters.

1. *Sharing of information, data and statistics created between department established by the HA for the performance of their functions.*

The departments established by the HA are:

i. Department for Policy in Health;

ii. Department for Healthcare Services;

iii. Department for Health Regulation.

2. *Requests for information from data subjects*

Departments established under the HA may request all information from patients, relatives, personnel, and professionals, and from public and private healthcare providers, and such data shall be given to it in cases of emergency, for reasons of public health and to safeguard the vital interest of the patient or a third person. In all other cases the informed consent of the patient shall be required.

3. *Patient access to Medical Records*

Patients in Malta can also access their medical records in accordance with the DPA. In Malta access to such data is through online means.[1] Due to information being found online, the risk of data breaches increases. Access to such records is restricted with the requirement of explicit consent.

(E) Subsidiary Legislation 528.01 (Functions And Responsibilities Of Department For Policy In Health Regulations) permits the Department for Policy in Health Regulations to collate, analyse and publish epidemiological data concerning the health status of the nation in order to identify and prioritize healthcare needs.

(F) Subsidiary Legislation 528.03 (Cross-Border Healthcare Regulations) establishes the national contact point for cross-border healthcare and empower this contact point to be the main point of reference for all matters related to information on cross-border healthcare including provision of information to patients, patients' organisations, healthcare providers, healthcare insurers and other contact points of other Member States. This may also include patient data in relation to ensuring there is proper provision of health care on a cross border basis in relation to a patient.

(G) Subsidiary Legislation 528.04 (Functions and Responsibilities of Department of Health Services Regulations provides that the Department of Health Services is responsible to ensure the effective and efficient operation

[1] Accessing Health Records:

<https://www.gov.mt/en/Services-And-Information/Business-Areas/Health%20Services/Pages/Health-Records.aspx>

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and delivery of healthcare services with an emphasis on clinical and corporate governance, service delivery and quality review, in particular by , inter alia, promoting research, teaching and training.

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

Article 14 of the GDPR specifically provides that certain information is to be provided to the data subject where the personal data is collected from other sources

a) the identity and contact details of the controller;

b) the contact details of the data protection officer where applicable;

c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;

d) the categories of personal data concerned;

e) the recipients or categories of recipients of the personal data if any;

f) transfers of personal data;

g) the period for which data will be stored;

h) existence of data subject rights;

i) existence of right to withdraw consent;

j) right to lodge complaint with supervisory authority;

k) from which source personal data originated, and if applicable, whether it came from public sources;

l) the existence of automated decision-making, including profiling and information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

The controller shall provide this information within a reasonable period after obtaining the personal data, but at the latest within one month. If the personal data is used for communication with the data subject, such information must be provided at the latest at the time of the first communication to the data subject or if a disclosure is envisaged, at the latest when the personal data is first disclosed.

However Article 14(4) provides that the above obligations shall not apply where and insofar as the data subject already has the information or the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for scientific research purposes, subject to the conditions and

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safeguards referred to in Article 89(1) of the GDPR or in so far as such an obligation is likely to render impossible or seriously impair the achievement of the objectives of that processing.

Therefore, in case of processing of personal data for research purposes, the obligation to inform data subjects where such personal data is not directly collected from the data subject, the obligation to inform the data subject can be held to represent a disproportionate effort and this obligation would no longer subsist. However, if such a derogation is used, processing must 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 order to ensure respect for the principle of data minimisation. Those measures may include pseudonymimsation provided that those purposes can be fulfilled in that manner. Where those purposes can by fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in such a manner.

The Directorate for Health Information and Research ("**DHIR**") is responsible for the the collection, analysis and delivery of health related information in Malta. It provides high quality **epidemiological information** and **indicators** on the health of the population and health services. It may make available health information for policy and decision makers, for the public in general, interested institutions and others that may require it. It is possible to submit a form requesting aggregate data for health research purposes, available on the DHIR website. In order to request patient identifiable data, an appointment must be made with the DHIR in order to discuss this request. In order for such a request to be granted the Request for Records level data files form and the Request for Record level data form must be submitted. The latter form specifies that proof of consent must be obtained from data subjects.

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?

The previous Data Protection Act was repealed and revoked following the entry into force of GDPR. This was replaced by the DPA which implements the provisions of the GDPR in their entirety. To date, the other legislation referred to as well as the practices of the DHIR have remained unchanged. 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?

In Malta, as specified in Article 11 of the DPA, the role of the supervisory authority is performed by the the Information and Data Protection Commissioner (the "**IDPC**"). The IDPC is responsible for monitoring and enforcing the application of the provisions of the DPA and the GDPR in order to protect the fundamental rights and freedoms of natural persons in relation to processing of personal data and to facilitate the free flow of personal data between Malta and any other Member State. As regards the processing of health data for research purposes, Article 7 of the DPA provides that prior authorisation of the IDPC is required prior to collecting heath data for research purposes.

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The HEC acts as an advisory committee in this regard, however the decision to authorise such collection of health data is within the remit of the IDPC.

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

The role of the IDPC has remained unchanged following the entry into force of the GDPR under the new DPA.

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

Art. 8.4 of Directive 95/46: "4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."

a. Transposition of Article 8.4 of Directive 95/46

In Malta, the exemptions in the Data Protection Act are very similar to those found in Article 8.4 of the Directive. The data concerning health is classified under Sensitive Personal Data[2] in the DPA. It is emphasized that such data can only be processed with the explicit consent of the data subject and where the data subject has made the data in question public.

In addition, processing of sensitive personal data is permitted in order that the controller may fully comply with his duties or exercise his rights under any law regulating the conditions of employment, or in order to protect the vital interests of the data subject or some other person and the data subject is not capable (whether physically or legally) of giving consent, or where the processing is required for the establishment, exercise or defence of legal claims.

The DPA also provides that sensitive personal data may be processed for health and hospital care purposes, provided that it is necessary for:

(a) preventive medicine and the protection of public health;

(b) medical diagnosis;

(c) health care or treatment; or

(d) management of health and hospital care services:

[2] Referred to as "special categories of data" in both the Directive and the GDPR

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Provided that the data is processed by a health professional or other person subject to the obligation of professional secrecy.

Similarly, processing of sensitive personal data is permitted for research and statistical purposes provided it is necessary for the performance of an activity that is carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data is disclosed. This is also subject to approval by the IDPC acting in accordance with its advisory body as explained below.

In terms of the Clinical Trials Regulations (Subsidiary Legislation 458.43), a clinical trial[3] may only be conducted where informed consent has been given and provided the rights of a subject to privacy and to the protection of the data concerning him in accordance with the Data Protection Act and any amendments thereto, are safeguarded.[4]

There have been no specific exemptions formulated, however, in guidance issued by the IDPC, the processing of sensitive personal data should also be done after informed consent of the data subject has been obtained. Where consent is not a prerequisite (e.g. in cases where the researcher is empowered by a specific law), data subjects should at least be informed on the purposes for which their personal data will be processed and also any recipients to whom it may be disclosed. Data subjects should also be informed about the right to request access to the personal data and where applicable, the erasure or deletion of such information. In the IDPC's guidelines, where research involves sensitive data, processing may occur with the explicit consent of the individual or where such research is in the public interest, it may be carried out with the approval of the IDPC after consulting a research ethics committee. For the purposes of approving medical research, the IDPC recognises the Health Ethics Committee ("**HEC**") which falls under the Superintendent of Public Health which acts as the IDPC's advisory body in this respect. The researcher must submit an application at the HEC which is evaluated by the HEC both on ethical as well as data protection aspects. Once approved, the project is forwarded to the IDPC for formal endorsement. The application form is accessible here:

To date, the Clinical Trials Regulations (Subsidiary Legislation 458.43) have not been amended and the IDPC guidance and HEC applications have remained the same after the entry into GDPR.

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?

No, there is no specific legal regime applying to data processing for research in the field of health and accordingly, such data must be processed in accordance with the provisions of the DPA and the GDPR. As explained above, in

[3] Clinical trial means any investigation in human subjects intended to discover or verify the clinical, pharmacological and, or other pharmacodynamic effects of any investigational medicinal product and, or to identify any adverse reactions to any investigational medicinal product and, or to study absorption, distribution, metabolism and excretion of any investigational medicinal product with the object of ascertaining its safety and, or efficacy. This includes clinical trials carried out in either one site or multiple sites, whether in one or more than one Member State;

[4] Clinical Trials Regulations (Subsidiary Legislation 458.43), Article 4(1)(b).

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accordance with the IDPC's guidelines there is a procedure in place for the application and approval of health research subject to the requirements indicated.

From which generally applicable data protection provisions are researchers exempted and under what conditions?

Article 6 of the DPA provides that subject to appropriate safeguards for the rights and freedoms of the data subject, including pseudonymisation and other technical and organisational measures to ensure respect for the principle of data minimisation, controllers may derogate from the following obligations for the processing of personal data for scientific research purposes:

- the right of access by the data subject under Article 15 of the GDPR;
- the right to rectification under Article 16 of the GDPR;
- the right to restriction of processing under Article 18 of the GDPR; and
- the right to object under Article 21 of the GDPR.

These rights can only be derogated from insofar as the exercise of such rights: (a) is likely to render impossible or seriously impair the achievement of those purposes; and (b) the data controller reasonably believes that such derogations are necessary for the fulfilment of those purposes.

In addition, where the purposes for processing data can be fulfilled by processing which does not permit, or no longer permits, the identification of data subjects, such purposes shall be fulfilled in this manner.

Article 23 of the GDPR also provides that Member States may restrict the scope of the obligations and rights provided for in Articles 12 to 22 and Article 34, as well as Article 5 in so far as its provisions correspond to the rights and obligations provided for in Articles 12 to 22, when such a restriction respects the essence of the fundamental rights and freedoms and is a necessary and proportionate measure on a democratic society to safeguard inter alia, important objectives of general public interest, including public health.

In furtherance of Article 23 of the GDPR, Article 4 of the Restriction of the Data Protection (Obligations and Rights) Regulations (S.L 586.09) provides that restrictions on the rights contemplated under Articles 15, 16, 18 and 21 will apply where such restrictions are a necessary measure required for health data that is processed and where it is likely that the application of the rights and obligations would cause serious harm to the vital interests of the patient.

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

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

The exemption under Article 8.4 of the Directive was not availed of.

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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?

(i) Professional Secrecy

Recital 164 of the GDPR provides that as regards the powers of the supervisory authorities to obtain from the controller or processor access to personal data and access to their premises, Member States may adopt by law, within the limits of the Regulation, specific rules in order to safeguard the professional or other equivalent secrecy obligations, in so far as necessary to reconcile the right to protection of personal data with an obligation of professional secrecy.

To date, no such national legislation has been enacted.

In terms of the Professional Secrecy Act (Cap 377 of the Laws of Malta), the following persons are subject to professional secrecy: members of a profession regulated by the Medical and Kindred Professions Ordinance, advocates, notaries, legal procurators, social workers, psychologists, accountants, auditors, employees and officers of financial and credit institutions, trustees, officers of nominee companies or licensed nominees, persons licensed to provide investment services under the Investment Services Act, stockbrokers licensed under the Financial Markets Act, insurers, insurance agents, insurance managers, insurance brokers and insurance sub-agents, officials and employees of the State.

The Criminal Code (Cap 9 of the Laws of Malta) provides that if any person which by reason of his calling, profession or office becomes the depositary of any secret confided in him, shall except when compelled by law to give information to a public authority, disclose such secret, he shall in conviction be liable to a fine not exceeding forty-six thousand and five hundred and eighty-seven euro and forty-seven cents (46,587.47) or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.

(ii) Express consent for specific data

There are guidelines issued regarding research on patients and the requirement for consent. Specifically, the Patient's Charter provides that, in relation to research, a data subject has a right to be informed and to, completely free of coercion, determine whether to accept, decline or withdraw participation in clinical research or student training.[5]

(iii) Deceased data subjects

Data protection laws do not apply to deceased data subjects.

Nevertheless, the Malta Statistics Authority Act (Chapter 422 of the Laws of Malta) provides that no information obtained in any way under this Act relating to an identifiable person or undertaking shall, except with the written consent of that person or undertaking or the personal representative or next-of-kin of that person, ***if he be deceased***, be disseminated, shown or communicated to any person or body except (a) for the purposes of a prosecution for an offence under this Act, or(b) to officers of statistics in the course of their duties under this Act.[6]

[5] Principle 4(1) of the Patient's Charter

[6] Article 41(1) of Malta Statistics Authority Act

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(iv) specific provisions for minors or persons subject to guardianship?

The DPA is silent with respect to minors and the provision of consent. Article 8 of the GDPR as well as national laws, in particular the Processing of Child's Personal Data in relation to the Offer of Information Society Services Regulations (Subsidiary Legislation 586.11) only regulate the processing of personal data of minors in relation to the offer of information society services. As regards the consent of minors in relation to other data processing, , one would need to consider the general principles of contract law outlined under the Civil Code (Chapter 16 of the Laws of Malta), in particular the provisions regulating legal capacity. As a matter of Maltese law, a minor is not consider to be lawfully capable of giving consent as the minor is not considered to have legal capacity to contract. Therefore, any consent given by a minor without the authority of his or her parents or legal guardian would not be valid consent There is a slight derogation from this general rule where obligations entered into by the minor are not null if they are entered into by a minor between the age of 14 and 18 and the minor is not (i) subject to parental authority; or (ii) under the tutorship of a curator.

Therefore, where this derogation does not apply, consent of the parent or legal guardian on behalf of the minor would need to be obtained.

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

Article 13 of the GDPR provides that certain information is to be provided to the data subject including:

a) the identity and contact details of the controller;

b) the contact details of the data protection officer where applicable;

c) the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;

d) the categories of personal data concerned;

e) the recipients or categories of recipients of the personal data if any;

f) transfers of personal data

g) the period for which data will be stored

h) existence of data subject rights

i) existence of right to withdraw consent

j) right to lodge complaint with supervisory authority

k) the existence of automated decision-making, including profiling and information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject

Recital 62 of the GDPR provides that this obligation does not apply where the provision of information to the data subject proves to be impossible or would involve a disproportionate effort. This could in particular be the case where

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processing is carried out for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. In such cases, the number and age of the data subject and any appropriate safeguards are taken into consideration.

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?

The GDPR imposes fines of up to EUR 20 million or 4% or annual global turn over, whichever is the higher.

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

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?

The formality of notifying the IDPC prior to commencing processing has been abolished following the entry into force of GDPR.

It is also pertinent to consider the Clinical Trials Regulations which stipulate certain conditions for the conduct of clinical trials on subjects. The conditions stipulated are largely not relevant to privacy and data protection law save that:

- informed consent needs to be given by the data subject – this needs to be written unless the data subject is unable to write. In such a case, oral consent may be given in the presence of at least one witness;
- a data subject needs to be informed of his right to withdraw from the trial at any time by revoking his informed consent without suffering any detriment; and
- the rights of the data subject to privacy and to the protection of the data concerning him in accordance with the DPA and any amendments thereto, are safeguarded.

In those cases where the data subject is not able to give informed consent, his legal representative may give his written consent after being informed of the nature, significance, implications and risks of the clinical trial.

Additionally, the data subject needs to be provided with a contact point where he may obtain further information.

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

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

In terms of the GDPR, personal data may not be processed for any purpose that is incompatible with that for which the information is collected. Notwithstanding this general limitation, Article 5(d) of the GDPR provides that further

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processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be regarded as incompatible with the initial purposes for which the personal data was collected.

In such a case, the data controller needs to ensure that there are appropriate safeguards for the rights and freedoms of data subject in place. Such 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.

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

Processing of scientific research for health purposes would fall within the scope of Article 5(d) of the GDPR and therefore further processing would not be considered to be incompatible with the purposes for which the personal data was collected, provided that the appropriate safeguards are implemented.

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

Generally speaking, Article 17 of the GDPR provides that the data subject has the right to obtain from the controller the erasures of personal data concerning him or her without undue deal and the controller shall have the obligation to erase personal data without undue delay in cases where the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed.

The data subject can also request the restriction of processing of his or her personal data rather than its erasure.

As regards the right to information pursuant to Article 14 of the GDPR, when the data is not collected from the data subject and is used for processing of statistical, historical or scientific purposes, this information need not be provided if providing it would involve a disproportionate effort or be impossible. However, such processing must 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 order to ensure respect for the principle of data minimisation. Those measures may include pseudonymimsation provided that those purposes can be fulfilled in that manner. Where those purposes can by fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in such a manner.

Similarly, the right of access does not apply where personal data is processed solely for purposes of scientific research or is kept in personal form for a period which does not exceed the period necessary for the sole purpose of compiling statistics.

This exemption does not apply where the data is used for taking measures or decisions regarding any particular individual or where there is a risk of breaching the privacy of the data subject.

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

Article 6 of the DPA provides that subject to appropriate safeguards for the rights and freedoms of the data subject, including pseudonymisation and other technical and organisational measures to ensure respect for the principle of

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data minimisation, controllers may derogate from the following obligations for the processing of personal data for scientific research purposes:

- the right of access by the data subject under Article 15 of the GDPR;
- the right to rectification under Article 16 of the GDPR;
- the right to restriction of processing under Article 18 of the GDPR; and
- the right to object under Article 21 of the GDPR.

The rights which are not excluded as regards the processing of personal data for scientific research purposes include the right to information under Articles 13 and 14 of the GDPR, the right to be forgotten pursuant to Article 17 of the GDPR, the right to object under Article 20 and the right not to be subject to a decision based on automated processing, including profiling which produces legal effects or similarly significantly affects him or her under Article 22 of the GDPR.

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

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?

Article 6 of the DPA provides that subject to appropriate safeguards for the rights and freedoms of the data subject, including pseudonymisation and other technical and organisational measures to ensure respect for the principle of data minimisation, controllers may derogate from the following obligations for the processing of personal data for scientific research purposes:

- the right of access by the data subject under Article 15 of the GDPR;
- the right to rectification under Article 16 of the GDPR;
- the right to restriction of processing under Article 18 of the GDPR; and
- the right to object under Article 21 of the GDPR.

These rights can only be derogated from insofar as the exercise of such rights: (a) is likely to render impossible or seriously impair the achievement of those purposes; and (b) the data controller reasonably believes that such derogations are necessary for the fulfilment of those purposes.

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In addition, where the purposes for processing data can be fulfilled by processing which does not permit, or no longer permits, the identification of data subjects, such purposes shall be fulfilled in this manner.

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

Once the controller has made a data protection impact assessment, and the results indicate high risks in the absence of measures taken to limit such risks, then the controller will consult the competent supervisory authority.[7] The Authority can take action within an eight week time period. However, Article 36 (5) of the GDPR leaves the opportunity to the Member States to further regulate this issue for processing carried out in the public interest, in particular for social protection and public health. It is still not clear weather Malta will further regulate the matter or not.

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

The general obligation to inform the IDPC that the controller intends to start processing operations has been abolished.

As regards, processing of personal data for health research purposes, Article 7 of the DPA provides that a data controller shall consult with, and obtain prior authorisation from, the Information and Data Protection Commissioner where the controller intends to process genetic data, biometric data or data concerning health for statistical or research purposes and in cases where such data are required to be processed for research purposes, the Information and Data Protection Commissioner shall consult a research ethics committee or an institution which has been duly recognised. For the purposes of approving medical research, the IDPC recognises the Health Ethics Committee ("**HEC**") which falls under the Superintendent of Public Health which acts as the IDPC's advisory body in this respect. The researcher must submit an application at the HEC which is evaluated by the HEC both on ethical as well as data protection aspects. Once approved, the project is forwarded to the IDPC for formal endorsement.

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

Article 89 (2) GDPR provides the opportunity of derogations to: the right to access the data by the data subject, the right to rectify, the right to restrict the processing and the right to object. However, these derogations are only available if those rights would seriously impair or make impossible the scientific purpose of the processing.

Article 6 of the DPA provides that subject to appropriate safeguards for the rights and freedoms of the data subject, including pseudonymisation and other technical and organisational measures to ensure respect for the principle of data minimisation, controllers may derogate from the following obligations for the processing of personal data for scientific research purposes:

- the right of access by the data subject under Article 15 of the GDPR;

[7] Article 35 and 36 GDPR.

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- the right to rectification under Article 16 of the GDPR;
- the right to restriction of processing under Article 18 of the GDPR; and
- the right to object under Article 21 of the GDPR.

The rights which are not excluded as regards the processing of personal data for scientific research purposes include the right to information under Articles 13 and 14 of the GDPR, the right to be forgotten pursuant to Article 17 of the GDPR, the right to object under Article 20 and the right not to be subject to a decision based on automated processing, including profiling which produces legal effects or similarly significantly affects him or her under Article 22 of the GDPR.

However, as regards Article 14 of the GDPR, the obligation to inform data subject where the personal data has not been collected directly from him or her, in case of processing of personal data for research purposes, the obligation to inform data subjects where such personal data is not directly collected from the data subject, the obligation to inform the data subject can be held to represent a disproportionate effort and this obligation would no longer subsist. However, if such a derogation is used, processing must 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 order to ensure respect for the principle of data minimisation. Those measures may include pseudonymimsation provided that those purposes can be fulfilled in that manner. Where those purposes can by fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in such a manner.

Article 35(3) of the GDPR provides that a data protection impact assessment is required in the case of processing on a large scale of special categories of data, including health data. To date, the supervisory authority has not issued any guidance in this respect however is expected to issue them shortly.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing can be defined as “the processing of personal data for purposes other than those for which the personal data has been initially collected”. Further processing is allowed only when its purpose is compatible with the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. For example, if personal data is initially processed based on the data subject’s consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorising the further processing of the same data.

How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by Article 6 (4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the

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further processing is "compatible". This is particularly relevant to big data analytics. Article 6 (4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject's consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing's purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under Article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller, and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under Article 5 (1) (b) of the GDPR the compatibility of the processing purpose of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily imagined. Scientific research is very often based on existing data, this is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This assumption made for the benefit of scientific research is linked to the derogation of the principle of data minimisation for scientific research purposes. However, this presumption is limited by some requirements, which are set out in Article 89(1) of the GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organisational measures, such as pseudonymisation. Although a different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: "The further processing of personal data for (…) scientific (…) research purposes (…) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."

Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject".

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

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The provisions of the GDPR have been implemented in their entirety, and in this respect the DPA makes no changes to the position under GDPR.

6. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

The DPA does not currently contain specific provisions for anonymised or pseudonymised health data. Accordingly, when considering this type of information one would need to look to the provisions of the GDPR which will be directly applicable in Malta.

Personal data which has been truly anonymised does not fall within the ambit of the Regulation, hence such Regulation becomes inapplicable.[8]

On the other hand pseudonymisation of data is defined in Article 4 as "*the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person*"[9].

Pseudonymised data is considered to be an efficient method of security when processing. It is the controllers and processors who should put such a method into action in order to protect data subjects from being subjected to additional risks.[10]

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

- **DIRECT COLLECTION FROM 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.

The current legal framework for the processing of health data is that established by the GDPR.

Article 9(2) (j) of the GDPR provides that processing 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

[8] Recital 26 GDPR

[9] Article 4 GDPR

[10] Article 32 GDPR

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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.

In turn, Article 89(1) of the GDPR provides processing for archiving purposes in the public interest, scientific or historical research purposes of 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 order to ensure respect for the principle of data minimisation. Those measures may include pseudonymimsation provided that those purposes can be fulfilled in that manner. Where those purposes can by fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in such a manner. Therefore, pursuant to the above, the processing of health data for scientific research purposes is considered to be lawful. However, such processing must be subject to appropriate safeguards for the rights and freedoms of data subjects.

The manner in which such personal data is collected should be proportionate to the aims pursued and in case of large-scale processing of health data, a Data Protection Impact Assessment shall be required.

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 legal framework currently in force is that established by the GDPR with no relevant departures from the principles of data processing established by the 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.

No specific rules for obtaining health data are stipulated under the DPA save that this processing is permitted provided the data is processed by a health professional or other person subject to the obligation of professional secrecy. As stated, it is possible to request the DHIR for either aggregate medical data, which request is not subject to approval, or else patient-specific medical records however, such a request is subject to approval and authorisation. Moreover, the provisions of the DPA and the GDPR are applicable to such requests.

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 procedures and rules under the DPA have changed to reflect the provisions of the GDPR in their entirety.

- **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.

No specific rules are stipulated and accordingly, the provisions of the DPA and subsidiary legislation enacted thereto would apply.

Under the 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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The procedures and rules under the DPA have changed to reflect the provisions of the GDPR in their entirety.

- **PUBLIC DATABASES**

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

This data that is made available is statistical anonymised information. This is available through the Hospitals Information System (NHIS). The NHIS collects hospital activity data from State and Private Hospitals for the purposes of collating hospital health data requests.

The statistical data is available online, however, given that this is anonymised, the provisions of the DPA would not apply.

Patients in Malta can also access their medical records in accordance with the DPA. In Malta access to such data is through online means.[11]

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 procedures and rules under the DPA have changed to reflect the provisions of the GDPR in their entirety.

b. Application of the national framework to the AEGLE cases

In the AEGLE project, the"research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic LymphoticLeukemia (CLL), Intensive Care Units and type 2 diabetes for the prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models".[12]

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

1. Type 2 diabetes

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

[11] Accessing Health Records:

<https://www.gov.mt/en/Services-And-Information/Business-Areas/Health%20Services/Pages/Health-Records.aspx>

[12] AEGLE Grant Agreement, Annex 1, p. 83.

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While no current rules exist in this regard and the provision of the DPA and the guidelines referred to above would apply, the researcher should also obtain the informed consent from the data subject, clearly explaining the reason for processing.

The DPA permits processing of sensitive personal data for health and hospital care purposes, provided that it is necessary for:

(a) preventive medicine and the protection of public health;

(b) medical diagnosis;

(c) health care or treatment; or

(d) management of health and hospital care services:

Provided that the data is processed by a health professional or other person subject to the obligation of professional secrecy.

Therefore, the researcher would need to be subject to the obligation of professional secrecy.

If the researcher is not subject to professional secrecy, then informed and explicit consent from the data subject should be obtained.

Please also bear in mind that there is an issue of secondary processing given that the data has been collected by the medical professional treating the data subject. Therefore an analysis behind the purpose of collection of such data (treatment of a data subject) and whether the use of the same data for research purposes fall within the purpose limitation outlined under the DPA. Broadly , the purposes can be seen to be the same given that they both relate to use of data for treatment (either on a specific level or a holistic level). However, the medical professional should obtain the informed consent of the data subject (who may oppose it) and the researcher should be subject to professional secrecy.

Since Maltese law has not yet been amended and no bill has yet been put forward, the answer to this question cannot be answered so far within the context of Maltese law implementation of the GDPR and therefore, the provisions of the GDPR as they currently stand will apply.

A notification of processing activities should also be filed at the IDPC by the researcher prior to the commencement of processing operations (if the DPA is applicable to the researcher).

2. Intensive Care Unit (ICU)

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

The DPA currently doesn't contain provisions of pseudonymisation. However, given that the provisions of the GDPR apply to pseudonymisation, the conclusion to be drawn is that the provisions of the DPA apply to pseudonymised data.

As outlined above, the DPA contains provisions permitting the processing of sensitive personal data may for health and hospital care purposes, provided that it is necessary for:

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(a) preventive medicine and the protection of public health;

(b) medical diagnosis;

(c) health care or treatment; or

(d) management of health and hospital care services:

Provided that the data is processed by a health professional or other person subject to the obligation of professional secrecy.

Therefore, the researcher would need to be subject to the obligation of professional secrecy.

If the researcher is not subject to professional secrecy, then informed and explicit consent from the data subject should be obtained.

Please also bear in mind that there is an issue of secondary processing given that the data has been collected by the medical professional treating the data subject. Therefore an analysis behind the purpose of collection of such data (treatment of a data subject) and whether the use of the same data for research purposes fall within the purpose limitation outlined under the DPA. Broadly , the purposes can be seen to be the same given that they both releate to use of data for treatment (either on a specific level or a holistic level). However, the medical professional should obtain the informed consent of the data subject (who may oppose it) and the researcher should be subject to professional secrecy.

A notification of processing activities should also be filed at the IDPC by the researcher prior to the commencement of processing operations (if the DPA is applicable to the researcher).

Since Maltese law has not yet been amended and no bill has yet been put forward, the answer to this question cannot be answered so far within the context of Maltese law implementation of the GDPR and therefore, the provisions of the GDPR as they currently stand will apply.

3. Chronic Lymphocytic Leukemia (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.

As outlined above, the DPA contains provisions permitting the processing of sensitive personal data may for health and hospital care purposes, provided that it is necessary for:

(a) preventive medicine and the protection of public health;

(b) medical diagnosis;

(c) health care or treatment; or

(d) management of health and hospital care services:

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Provided that the data is processed by a health professional or other person subject to the obligation of professional secrecy.

Therefore, the researcher would need to be subject to the obligation of professional secrecy.

If the researcher is not subject to professional secrecy, then informed and explicit consent from the data subject should be obtained – therefore, explicit consent should also be obtained.

As regards the issue of secondary processing one must determine whether the purpose of collection of such data (treatment of a data subject) and whether the use of the same data for research purposes fall within the purpose limitation outlined under the DPA. Broadly , the purposes can be seen to be the same given that they both relate to use of data for treatment (either on a specific level or a holistic level). However, the medical professional should obtain the informed consent of the data subject (who may oppose it) and the researcher should be subject to professional secrecy.

A notification of processing activities should also be filed at the IDPC by the researcher prior to the commencement of processing operations (if the DPA is applicable to the researcher).

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Qualifications

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