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C E L A B

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THE LEGAL REGULATION OF BIOBANKS

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GeneBanC

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CEU

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THE REGULATORY FRAMEWORK OF THE ESTABLISHMENT, MANAGEMENT AND FUNCTIONING OF BIOBANKS IN MALTA

As partners in the European Union Framework Project entitled "GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data" we are exploring the legal regulations of genetic databanks. (http://www.genebanc.eu/) The Center for Ethics and Law in Biomedicine established at the Central European University, Budapest (http://www.ceu.hu/celab) aimed to investigate the existing regulatory framework of biobanks across the EU and to focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European practices and regulations. The European jurisdiction was divided up into two parts between CELAB and the Belgian project partner, the Centre for Biomedical Ethics and Law, K.U.Leuven. CELAB was focusing on the regulatory framework of Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic and Slovenia.

In the framework of the research, we have prepared questionnaires, which we sent out to national experts in the field. We are very grateful to Dr Bridget Ellul MB ChB, FRCPath, MRCPath, Head of the Department of Pathology and Senior Lecturer in Forensic Pathology and to John Charles Ellul BA MBA, Police Inspector at the Forensic Science Laboratory, for providing us with useful information.

The present booklet summarizes the regulatory framework of biobanks in Malta and focuses on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical and forensic biobanks. The former will be discussed in Part I, whereas forensic biobanks invoking legal issues of different nature will be covered separately in Part II. The present analysis does not cover either international standards, or pieces of European Union law, but it should be borne in mind that they are binding on Malta being a European Union Member State.

Budapest, 31 July 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

Malta has not adopted any special legislation for the regulation of biobanks. The lack of a special regulative framework on the establishment and management of biobanks resulted in a fragmented legislative structure of generally applied constitutional provisions, laws, regulations, legal notices, codes of practice, guidelines and so forth, which are potentially applicable to biobanks.

The term biobank has not been officially defined in Maltese law. Nevertheless, Article 2 of Act IV of 2006 on regulating the collection and testing of human blood and blood components and establishing standards of quality and safety for human tissues and cells intended for human transplants (hereinafter referred to as Human Blood and Transplants Act[1]) sets out the definition of "tissues and cells establishment" which "[...] means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells" (hereinafter referred to as tissue bank or tissue establishment). It is also worth mentioning that the Human Blood and Transplants Act has transposed all the relevant EU Directives concerning the regulation of biobanks.

2. RELEVANT LAWS

As it is already mentioned, Malta has not established any specific legislation concerning biobanks and the relevant legal regulation consists of generally applied provisions of legal instruments.

The area that is most comprehensively covered is transplantation. Transplantation standards for the quality and safety of tissues and cells throughout the transplantation process are set in Maltese legislation via the Human Blood and Transplants Act (Act IV of 2006), furthermore through the Tissues

[1] Human Blood and Transplants Act (Cap. 483) To regulate the collection and testing of human blood an blood components and to establish standards of quality and safety for human tissues and cells intended for human transplants. 15th September, 2006, Act IV of 2006, as amended by Legal Notice 427 of 2007. In original language: Kapitolu 483, Att dwar id-Demm Uman u Trapjanti. Biex jirregola t-teħid u l-eżami ta' demm uman u komponenti taddemm u biex jistabbilixxi livelli ta' kwalità u sigurezza għat-tessut u ċelloli umani intiżi għat-trapjanti fil-bniedem. 15 ta' Settembru, 2006 L-ATT IV ta' l-2006, kif emendat bl-Avviż Legali 427 ta' l-2007. Available at:
http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_15/Chapt483.pdf

and Cells (Quality and Safety) Regulations, 2006 (L.N.[2] 271 of 2006)[3] and the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations, 2007 (L.N. 337 of 2007)[4]. These legislations have transposed three Directives dealing with human tissues and cells that have been adopted by the Commission of the European Communities (Directive 2004/23/EC, Directive 2006/17/EC and Directive 2006/86/EC). The Tissues and Cells (Quality and Safety) Regulations, 2006 L.N. 271 of 2006 transpose Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and Directive 2006/17/EC as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. The Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations, 2007, (L.N. 337 of 2007) transpose Commission Directive 2006/86/EC which implements Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

The Blood Quality and Safety Regulation of 2006 (L.N. 272 of 2006)[5] implements the requirements of three EU Directives: Directive 2002/98/EC (setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components), Directive 2004/33/EC (implementing Directive 2002/98/EC as regards certain technical requirements for blood and blood components) and Directive 2005/62/EC – implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments).

L.N. 273 of 2006 (Traceability Requirements and Notification of Serious

[2] L.N. means Legal Notices within the Maltese legislative framework.

[3] L.N. 271 of 2006 Human Blood and Transplants Act, 2006 (Act no. IV of 2006) Tissues and Cells (Quality and Safety) Regulations, 2006, Government Gazette of Malta No. 17,994 – 10.11.2006. In original language: A.L. 271 ta' l-2006 Att ta' l-2006 dwar id-Demm Uman u t-Trapjanti (Att Nru. IV Ta' l-2006) Regolamenti ta' l-2006 dwar il-Kwalità u s-Sigurezza tat-Tessut u ċ-Ċelloli. Available at: http://docs.justice.gov.mt/LegalPub/Legal_Publications\Legal_Notices\English\2006\271 - 2006 - P3830-3844.pdf

[4] Human Blood and Transplants Act (Cap. 483) Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations, 2007, Government Gazette of Malta No. 18,141 – 30.10.2007. In original language: A.L. 337 ta' l-2007 Att ta' l-dwar id-Demm Uman u t-Trapjanti (KAP. 483) Regolamenti ta' l-2007 dwar Tessuti u Celloli Umani (Kodifikazzjoni, Ipproċessar, Preservazzjoni, - Ħżin u Distribuzzjoni). Available at: http://docs.justice.gov.mt/LegalPub/Legal_Publications\Legal_Notices\English\2007\337 - 2007 - P4207-4232.pdf

[5] L.N. 272 of 2006 Human Blood and Transplants Act, 2006 (Act no. IV of 2006) Blood (Quality and Safety) Regulations, 2006, Government Gazette of Malta No. 17,994 – 10.11.2006. In original language: A.L. 272 ta' l-2006 Att ta' l-2006 dwar id-Demm Uman u t-Trapjanti (Att Nru. IV Ta' l-2006) Regolamenti ta' l-2006 dwar il-Kwalità u s-Sigurezza tad-Demm. Available at: http://docs.justice.gov.mt/LegalPub/Legal_Publications\Legal_Notices\English\2006\272 - 2006 - P3855-3864.pdf

Adverse Reactions and Events Regulations, 2006)[6] transposes Directive 2005/61/EC (implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events).

In addition to the Human Blood and Transplants Act and its related legal notices, Act XXVI of 2001 on making provision for the protection of individuals against the violation of their privacy by the processing of personal data and for matters connected therewith or ancillary thereto (hereinafter referred to as the Data Protection Act[7]) is also relevant in the respective legal domain. Biobanks contain not only biological samples but also personal data about the donor of the biological material such as data related to health and genetic data. Therefore one of the main legal instruments on their regulations is the Data Protection Act which transposed Directive 95/46/EC of the European Parliament and of the Council 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 into national legislation in 2001. The Maltese Data Protection Act was the first legislative instrument in Malta that regulates exclusively the protection of personal data and it was in compliance with Directive 96/46/EC even though at the time of its introduction Malta was not a Member State of the European Union. The Data Protection Act came into force on 15 July 2003.

Article 2 of the Data Protection Act lays down that "personal data that reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership of a trade union, health, or sex life" are considered to be sensitive. The individual's genetic information that might be regarded as part of his or her health status, is also deemed to be sensitive personal data, though there is no explicit reference to them in Article 2.

According to the Data Protection Act sensitive personal data is subjected to special rules hence Article 12 Section (1) sets forth that any processing of sensitive data is prohibited. The processing of such data can only take place under certain conditions specified in Article 12 Section (2), and Articles 13 to 16 of the Data Protection Act (see *infra*) in line with the relevant provisions of Directive 95/46/EC. Addi-

[6] L.N. 273 of 2006 Human Blood and Transplants Act, 2006, (Act no. IV of 2006) Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations, 2006, Government Gazette of Malta No. 17,994 – 10.11.2006, In original language: A.L. 273 ta' l-2006 Att ta' l-2006 dwar id-Demm Uman u t-Trapjanti (Att Nru. IV Ta' l-2006) Regolamenti ta' l-2006 dwar Ħtiġiet ta' Traċċabilità u Avviż ta' Reazzjonijiet u Okkorrenzi Gravi Avversi. Available at: http://docs.justice.gov.mt/LegalPub/Legal_Publications\Legal_Notices\English\2006\273 - 2006 - P3876-3886.pdf

[7] Data Protection Act (Cap. 440) To make provision for the protection of individuals against the violation of their privacy by the processing of personal data and for matters connected therewith or ancillary thereto. Act XXVI of 2001, as amended by Acts XXXI of 2002 and IX of 2003; and Legal Notices 181 and 186 of 2006, and 426 of 2007. In original language: Kap. 440 Att dwar il-P rotezzjoni u l-Privatezza tad-Data Sabiex jagħmel provvedimenti għall-protezzjoni ta' individwi kontra l- ksur tal-privatezza tagħhom bl-ipproċessar ta' "data" personali u dwar dak li għandu x'jaqsam ma' dan jew li hu anċillari għalih. Government Gazette of Malta No. 17,175 - 14th December, 2001. Available at: http://docs.justice.gov.mt/lom/legislation/english/leg/vol_13/chapt440.pdf

tionally sensitive personal data can also be processed in circumstances specified in an order made by the Minister responsible for data protection with respect to important public interests.

Although the Maltese Constitution[8] does not provide explicit legal protection for the collection and processing of the individual's personal data, the Data Protection Act shall be interpreted together with the Maltese Constitution. Within the general provisions of Fundamental Rights and Freedoms of the Individual, Article 32 of the Maltese Constitution sets forth that "[...] every person in Malta is entitled to the fundamental rights and freedoms of the individual, that is to say, the right, whatever his race, place of origin, political opinions, colour, creed or sex, but subject to respect for the rights and freedoms of others and for the public interest, to each and all of the following, namely

a) life, liberty, security of the person, the enjoyment of property and the protection of the law;
b) freedom of conscience, of expression and of peaceful assembly and association; and
c) respect for his private and family life."

Act XVII of 2002, the so called[9] Professional Secrecy Act also proves to be important. Given the sensitivity of the genetic data collected for tissue banks or biobanks, confidentiality and legally established professional secrecy is considered of great significance. Professionals' confidentiality, including the obligation imposed on medical practitioners is also required by the Maltese Criminal Code,[10] Article 257 of which sets forth that if any person, who by reason of his calling, profession or office, becomes the depositary of any secret confided in him or her, shall, except when compelled by law to give information to a public authority, disclose such secret, he or she shall on conviction be liable to a fine (multa) not exceeding EUR 46,587.47 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment.

Apart of the above mentioned pieces of legislation, L.N. 490 of 2004, the so called Clinical Trials Regulation[11] transposed Directive 2001/20/EC into the Maltese national law and regulates the

[8] The Malta Independence Order, 1964, as amended by Acts: XLI of 1965, XXXVII of 1966, IX of 1967, XXVI of 1970, XLVII of 1972, LVII, LVIII of 1974, XXXVIII of 1976, X of 1977, XXIX of 1979, IV of 1987, XXIII of 1989; Proclamations Nos. II and VI of 1990; Acts XIX of 1991, IX of 1994; Proclamations IV of 1995 and III of 1996; Acts: XI of 1996, XVI of 1997, III of 2000, XIII of 2001, V of 2003, and XIV and XXI of 2007.. Entered into force: 21st September, 1964. In original language: Kostituzzjoni ta' Malta, Available at: http://docs.justice.gov.mt/lom/legislation/english/leg/vol_1/chapt0.pdf

[9] Professional Secrecy Act (Cap. 377) To establish general provisions protecting professional secrecy and to make consequential amendments to other laws. Act XXIV of 1994, as amended by Acts XVII of 1998, XVII of 2002 and X of 2004. In original language: Kap. 377 Att dwar Segrettezza Professionali Biex jagħmel disposizzjonijiet ġenerali dwar il-protezzjoni tas-segretezza professjonali u sabiex jagħmel emendi konsegwenzjali f 'liġijiet oħra. L-Att XXIV ta' l-1994, kif emendat bl-Atti XVII ta' l-1998, XVII ta' l-2002 u X ta' l-2004. Available at:
http://docs.justice.gov.mt/lom/legislation/english/leg/vol_10/chapt377.pdf

[10] Criminal Code (Cap. 9) To amend and consolidate the Penal Laws and the Laws of Criminal Procedure. 10th June, 1854. In original language: Kap. 9, Kodici Kriminali. Available at:
http://docs.justice.gov.mt/lom/legislation/english/leg/vol_1/chapt9.pdf

[11] L.N. 490 of 2004 Subsidiary Legislation 458.43 Clinical Trials Regulations, 26th November, 2004, Legal Notice 490 of 2004, as amended by Legal Notice 248 of 2007. In original language: Available at:
http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/458/43.pdf

conduct of clinical trials, including multi-centre trials on human subjects involving medicinal products as defined under the Medicines Act and in particular relating to the implementation of good clinical practice.

Furthermore it should be mentioned that the University Research Ethics Committee (UREC) at the University of Malta adopted the so-called University Guidelines[12] which is a set of guidance manuals for the UREC. The Guidelines set forth the ethical requirements of the research involving humans and also the sanctions that would apply in case the Guidelines are not followed.

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

According to Article 3 Sections (1)-(2) of the Human Blood and Transplants Act the Superintendent of Public Health[13] is the licensing and supervisory authority in relation to the establishment and operation of tissue banks (hereinafter referred to as Licensing Authority). The Director General Health within the Ministry of Health, is the head of the Health Division and is also the Superintendent of Public Health. The Director General Health is directly accountable to the Minister for all matters relating to health.

The Licensing Authority is entitled (a) to verify that the tissue bank is in compliance with the requirements set out under the Act and any regulations made thereunder; (b) to indicate activities which may be undertaken by the tissue bank; (c) to establish conditions applicable to tissue bank; (d) to issue, renew, amend, vary, suspend or revoke any licence that may be required by or under the Act; (e) to carry out inspections of tissue banks and organize control measures in such establishments regularly and in any case not less than once every two years; (f) to conduct such additional inspections of establishments as it considers necessary for the purpose of ensuring compliance with the requirements of the Human Blood and Transplants Act and any regulations made thereunder; (g) to inspect hospital blood banks to ensure that such banks and persons responsible for the management of such banks comply with the requirements of the Act and any regulations made thereunder; (h) to organize inspections and other control measures in case of any serious adverse event or reaction or suspicion thereof; (i) to establish guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance; (j) to establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been

[12] The 'Guidelines for UoM Research Ethics Committee' is available at: http://www.um.edu.mt/__data/assets/pdf_file/0008/53396/ethicsguidelines.pdf.

[13] See also The Public Health Act, Act XIII of 2003 to promote and protect health (Cap. 465). Dated 21 November 2003. In original language: Kap. 465 Att dwar is-saħħa Pubblika Biex jippromwovi u jipproteġi s-saħħa. L-Att XIII ta' l-2003, kif emendat bl-Att III ta' l-2004; u bl-AvviżLegali 427 ta' l-2007.Available at: http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_14/Chapt465.PDF

licensed; (k) to take all measures that may be necessary for the purpose of ensuring compliance with any of the provisions of the Act or regulations made thereunder.

The Licensing Authority is also entitled to delegate any of its above mentioned supervisory functions to the Medicines Authority established under the Medicines Act,[14] or any other authority or institution it deems competent.

The application for the grant of a licence with the aim of establishing tissue bank under Article 3 of the Human Blood and Transplants Act shall be in the form and contain the information as set out by the Licensing Authority and shall also be accompanied by the prescribed fee.

According to the granted licence the tissue bank is solely entitled to carry out activities as set out in Article 5. The activities referred to in Article 5 Section (1) are (a) the collection of human blood components; and (b) the testing of human blood components, in both cases irrespectively of their intended purpose; and (c) their preparation, storage and distribution when intended for transfusion. Article 5 Section (3) also declares that a licence shall not be required for (a) the storage and distribution of, and the performance of compatibility tests on blood and blood components exclusively for use within hospital facilities, including transfusion activities where such activities are performed by a hospital blood bank; or (b) any person carrying out any of the activities referred to in Article 5 Section (2) where that person carries out that activity on behalf of, and pursuant to, a contractual arrangement with - (i) a blood establishment which is licensed under Part III of the Human Blood and Transplants Act to carry out the activity in question; or (ii) a person responsible for the management of a hospital blood bank.

In accordance with the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations, 2007 a tissue bank shall, for the purposes of its accreditation, designation, authorisation or licensing, comply with the requirements set out in Schedule I to the regulation. Schedule I of L.N. 337 of 2007 lays down the requirements for accreditation, designation, authorisation or licensing of tissue establishments. The requirements are grouped into six parts referring to the (1) organization and management of a tissue bank; (2) personnel in tissue establishments; (3) equipment and materials used in an establishment; (4) facilities or premises; (5) documentation and records and finally (6) quality review.

In terms of Article 29 of the Data Protection Act a data controller, any person or organisation processing personal data, shall prior to carrying out any wholly or partially automated processing operations, notify the Data Protection Commissioner of such processing. The law establishes an annual notification fee of € 23.29 which is due by

[14] Act III of 2003 to make provision for matters connected with the manufacture, preparation and assembly, wholesale distribution, storage, destruction, disposal, advertising and authorisation of medicinal products and any activity connected therewith and the regulation of the sale of medicinal products, pharmacies and related pharmaceutical activities and for any other matters ancillary thereto or connected therewith. [Cap. 458] In original: Kapitolu 458 Att Dwar Il-Medi-Ini, available at http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_14/Chapt458.PDF

data controllers who are obliged to notify the Data Protection Commissioner about their processing operations.

According to Article 30 Section (1) of the Data Protection Act, data controllers are entitled to appoint a Personal Data Representative and in such case the notification to the Data Commissioner as set out in Article 29 Sections (1) and (3) shall not be required. The function of the Personal Data Representative is to independently ensure that the controller processes personal data in a lawful and correct manner and in accordance with good practice. It is the intention of the Data Protection Commissioner to recommend the publication of regulations to establish the qualifications regulating Personal Data Representatives. Personal Data Representatives appointed before the publication of the said regulations will have to meet the qualifications eventually incorporated in the regulation.

As it is mentioned before, Article 3 of the Human Blood and Transplants Act also lays down that the Licensing Authority is obliged to establish and maintain a publicly accessible register of tissue banks specifying the activities for which they have been licensed for.

It also has to be noted that the Human Blood and Transplants Act entered into force on 15 September 2006. Since the relevant legislation applicable for biobanks is rather novel, according to the questionnaire provided for the current research, no biobanks have been established so far under the Act and there are no legal requirements for existing biobanks.

The Laboratory of Molecular Genetics at the University of Malta has set up and is responsible for a biobank containing collections of DNA and other biological materials from individuals with a number of diseases, besides banking of DNA from Maltese newborn and senior citizens.

4. PECUNIARY ASPECTS

In Malta pecuniary aspects of the collection and storage of genetic data in biobanks or tissue banks is not covered by legal regulations. The donor's remuneration is not addressed in the legislation, nonetheless the current practice in relation to compensation is free collection of relevant data for university laboratories and pathology laboratories, but collection of cord blood samples by private companies is subject to payment.

Considering clinical trials undertaken on minors, Article 5 of the Clinical Trials Regulations sets forth that no incentives or financial inducements be given for the persons participating in a clinical trial except agreed compensation. In line with Article 6, the same provisions are applicable to incentives for the participation in clinical trials undertaken on persons who are incapable of giving informed legal consent. In addition to the above Article 7 Section (2) h) sets out that "in preparing its opinion, the Ethics Committee shall consider, in particular [...] provision for indemnity or compensation in the event of injury or death attributable to a clinical trial." The Clinical Trials Regulations do not specify the definition of compensation concerning the participation in such trials, however the aforementioned provisions suggest that the compensation serve as an agreed indemnification on-

ly if the trial subject has suffered injury or deceased due to a clinical trial. Nevertheless, according to the EFGCP Report on Malta in relation to the ethical review of protocols for clinical research projects, "the amount and procedure for compensation of study subjects is evaluated on a case by case basis. This includes a description of the amount paid for participation in the trial such as travel costs, loss of earnings and discomfort."[15]

5. CONSENT

According to Article 9 of the Data Protection Act personal data may only be processed in case the data subject consented to it. Article 2 sets out the definition of 'consent' according to which it "means any freely given specific and informed indication"of his or her wishes by which the data subject signifies his or her agreement to personal data relating to him or her being processed.

As it is mentioned above, genetic data can be considered as sensitive personal data. According to Article 12 Section (2) of the Data Protection Act sensitive personal data can be processed with one of the following conditions:

a) with the explicit consent of the data subject to processing; or
b) where the information on the sensitive personal data has been made public by the data subject.

In addition to the above, Article 13 sets forth that sensitive personal data can be processed if appropriate safeguards are adopted and the processing is necessary (a) for the purposes of exercising or performing any right or obligation which is conferred or imposed by law on the data controller in connection with employment; or (b) to protect the vital interests of the data subject or another person where consent cannot be given or the data subject is physically or legally incapable of giving his or her consent; or (c) it is necessary for the purposes of establishing, exercising or defending legal rights.

Part IV of the Data Protection Act lays down the legal regulations on data processing for specific purposes according to which the data processing deems to be lawful on the condition that it is carried out in the course of its legitimate activities by anybody or any association which exists for political, philosophical, religious or trade-union purposes and which is not established or conducted for profit, and the sensitive personal data relates only to individuals who are either members of the body or association or who have regular contact with it in connection with its purposes. Such data processing does not involve disclosure of the personal data to a third party without the consent of the data subject either (Article 14).

According to Article 15 sensitive personal data may also be processed for medical care purposes, provided that it is necessary for:

[15] European Forum for Good Clinical Practice (EFGCP) Report on the Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe, Report on Malta, updated in 2008. http://www.efgcp.be/Downloads/EFGCPReportFiles/Flow Chart Malta (revised) 08-03-01.pdf

a) the purposes of preventive medicine and the protection of public health;
b) medical diagnosis;
c) the provision of health care and treatment; or
d) the management of health care and hospital care services.

Data processing necessary for purposes specified in Article 15 shall be deemed to be lawful if it is undertaken by a health professional or other person who owes a duty of confidentiality which is equivalent to the one which would arise if that person was a health professional.

In line with Directive 95/46/EC, Article 16 also sets out that the processing of personal data can also take place for research and statistical purposes, provided that the processing is necessary in order to protect the vital interests of the data subject. Additionally, the precondition for collecting and processing of sensitive personal data in case of statistics is the prior consent of the Data Protection Commissioner and in the case of research, the prior permission of the Data Commissioner has to be based on the advice of the research ethics committee of an institution recognised by the Commissioner for the purposes of the Article.

In line with Article 19 of the Data Protection Act, the data controller shall provide the data subject from whom the data has been collected, with at least the information on the identity and habitual residence or principal place of business of the data controller, on the purposes of the processing for which the data are collected and any further related information (such as the recipients or categories of the recipients of data; whether the reply to any questions made to the data subject is obligatory or voluntary, as well as the possible consequence of failure to reply; and the existence of the right to access, the right to rectify, and, where applicable, the right to erase the data concerning him or her, and, insofar as such further information is necessary, having regard to the specific circumstances in which the data is collected, to guarantee fair processing in respect of the data subject). Moreover, Article 21 of the Data Protection Act established further obligations of the controller of personal data, according to which at the request of the data subject the data controller shall provide the data subject, without delay and without expense, with written information as to whether personal data concerning the data subject is processed. Nevertheless the request of the data subject has to be made at reasonable intervals. Part VI of the Data Protection Act sets forth certain exemptions from the above mentioned regulations. Article 23 Section (2) sets out that the provisions of Article 21 shall not apply when 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.

Consent should be the aftermath of an independently made decision. An independent and freely made decision requires that the individuals, from whom the biological specimens and samples are to be collected, have been provided with all the necessary information. The consent also has to be wholly voluntary and shall not be forced in any way.

According to Article 3 of the Clinical Trials Regulations an 'informed con-

sent' means a a dated and signed written decision in one of the official languages of Malta or in a language understandable to the clinical trial subject (or understandable to her or his legal representative) on freely taking part in a clinical trial, after being duly informed of the nature, significance, implications and risks of such trial. The fact that the clinical trial subject was informed accordingly has to be appropriately documented and must be signed by the trial subject if he or she is capable of giving consent or, where this person is not capable of giving consent, by his or her legal representative. Furthermore if the trial subject is unable to write, oral consent may be given in the presence of at least one witness. According to Article 12 of the University Guidelines for the University of Malta Research Ethics Committee[16] when obtaining the consent, the researcher shall inform the data subjects about the purpose of processing, and about their rights under the Data Protection Act, namely the right to access, the right to rectify, and where applicable the right of the data subjects to erase the data concerning them. Article 12 also sets out that the data subject may also request written information about his or her personal data being processed by the researcher. In order to enable the data subject to exercise his or her right of access, when obtaining consent the researcher shall provide his or her identity and habitual residence. The data subject has the right to request the researcher to correct, and where applicable erase personal data that has not been processed in accordance with the Data Protection Act. Article 23 Section (3) of the University Guidelines also sets forth that in the case of research on genetic material, the consent form must indicate under what conditions the participant is giving consent, if at all, to the use of this material in further studies.

Article 4 Point (b) of the Clinical Trials Regulations also sets forth that if the trial subject is not able to give informed consent, his or her legal representative, has the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and also has to be informed of the data subject's right to withdraw from the trial at any time by revoking his or her informed consent without suffering any detriment. The same Article of the Clinical Trials Act also declares that the trial subject or, when the person is not able to give informed consent, his or her legal representative has to give his or her written consent after being informed of the nature, significance, implications and risks of the clinical trial. In addition to the above if the individual is unable to write, oral consent may be given in the presence of at least one witness.

5.1. Consent of minors, people with limited capacity and deceased persons

According to Article 157 of the Civil Code a minor is a person of either sex who has not yet attained the age of eighteen years. Additionally Article 158 sets forth that any minor, whose parents have died or have forfeited

[16] See also Ethical Committees.

parental authority and who has not married, is subject to be placed under tutorship until he or she becomes of age or until he or she marries. Article 135 of Civil Code also sets forth that in all civil matters the parents jointly represent their born or to be born children.

According to Article 5 of the Clinical Trials Regulations, clinical trial on minors may only be undertaken if the informed consent of the parents or legal representative has been obtained, and the consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. Furthermore the minor has to receive information according to his or her capacity of understanding, from staff with experience with minors, regarding the trial, the risks and the benefits. Nevertheless, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to withdraw the consent from the clinical trial at any time shall be given due consideration by the investigator.

Upon the Data Protection Commissioner's recommendations to the government the "Processing of Personal Data (Protection of Minors) Regulations" [17] were adopted in 2004 establishing that the best interest of the minors prevails over the right to privacy.

Consequently the Regulations allow for any teacher, member of a school administration, or any other person acting *in loco parentis* or in a professional capacity in relation to a minor, to collect and in any other way process information without the need to request the parents' consent. However this is subject to the condition that said processing is required in the best interest of the minor. Article 2 Section (3) of L.N. 125 of 2004 sets out that in such a case, no parent or other legal guardian of the minor shall have access to any personal data held in relation to the minor. Therefore the right of access, which is generally exercised by the parents on behalf of the child, is suspended until this is deemed necessary in the best interest of the minor. Notwithstanding these exemptions, any processing under these regulations must be compliant with the data protection principles.

The University Guidelines provides in Article 15 Section (3)d that the informed consent will be sought from each prospective subject or the subject's legally authorized representative and when appropriate, the assent of children participating in the research should be obtained as well as the consent should be obtained in the case of children over 12 years of age.

In relation to clinical trials on persons incapable of giving informed legal consent, Article 6 of the Clinical Trial Act provides that all relevant requirements listed for persons capable of giving such consent shall also apply. Furthermore, clinical trials on incapacitated adults who have not given and not

[17] L.N. 125 of 2004, Data Protection Act (Cap. 440) Processing of Personal Data (Protection of Minors) Regulations, 2004. In original language: A.L. 125 ta' l-2004 Att dwar il-Protezzjoni u l-Privatezza tad-Data (Kap. 440) Regolamenti ta' l-2004 dwar l-Ipproċessar ta' Data Personali Dwar MinurAvailable at: http://docs.justice.gov.mt/LegalPub/Legal_Publications\Legal_Notices\English\2004\125 - 2004 - P1582.pdf

refused informed consent before the onset of their incapacity, shall only be allowed to participate in a clinical trial if the informed consent of the legal representative has been obtained. Consent must represent the subject's presumed will and may be revoked at any time, without detriment to the subject. In line with the provisions concerning clinical trials on minors, the person not able to give informed legal consent shall receive information according to his or her capacity of understanding regarding the trial, the risks and the benefits. The Clinical Trials Regulation also declares that the interests of the patient always prevail over those of science and society.

6. ACCESS TO DATA OR SAMPLES, AND ANONYMITY

Article 27 of the Data Protection Act sets forth the main regulation concerning personal data transfer to a third country. Data processing to third countries that is undergoing processing or intended processing, may only take place subject to the provisions of the Data Protection Act and provided that the third country to which the data is transferred ensures an adequate level of protection. The adequate level of a third country's data protection is subject to the decision of the Data Protection Commissioner. The decision shall be assessed with a special view to the surrounding circumstances of the data transfer operation or a set of data transfer operations. In addition to the above particular consideration shall be given to the nature of the data, the purpose and duration of the proposed processing operation or operations, the country of origin and country of final destination, the rules of law, both general and sectoral, in force in the third country in question and the professional rules and security measures which are complied within that country.

Certain exemptions are provided by Article 28 of the Data Protection Act from the requirements of the transfer of data to third countries. The relevant article of the Act sets out that personal data transfer to a third country that does not ensure an adequate level of protection may be effected by the controller if the data subject has given his or her unambiguous consent to the proposed transfer or if the transfer

a) is necessary for the performance of a contract between the data subject and the controller or the implementation of precontractual measures taken in response to the data subject's request;
b) is necessary for the performance or conclusion of a contract concluded or to be concluded in the interests of the data subject between the controller and a third party;
c) is necessary or legally required on public interest grounds, or for the establishment, exercise or defence of legal claims;
d) is necessary in order to protect the vital interests of the data subject; or
e) is made from a register that according to laws or regulations is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate legitimate interest, provided that the conditions laid down by law for consultation are fulfilled in the particular case.

Furthermore, the Data Protection Commissioner is also entitled to authorize transfer of personal data to third countries if the controller provides adequate safeguards, which may result particularly by means of appropriate contractual provisions, with respect to the protection of the privacy and fundamental rights and freedoms of individuals and with respect to their exercise.

In relation to good information handling practice in a research project, Point 13 of the University Guidelines declares that personal data shall not be retained for a period longer than necessary and all measures shall be taken to anonymise data if possible and ensure confidentiality.

7. STORAGE

The Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulation, 2007 sets out that a tissue establishment shall, for the purposes of its accreditation, designation, authorisation or licensing, comply with the requirements laid down in Schedule I to the regulation.

According to Schedule I, Section 8 of the L.N. 337 of 2007, records on the operation of the tissue bank must meet the confidentiality requirements laid down in Article 14 of Directive 2004/23/EC. Access to registers and data must be restricted to persons authorised by the responsible person, and to the competent authority for the purpose of inspection and control measures. Article 14 of Directive 2004/23/EC sets forth that Member States shall take all necessary measures to ensure that all data have been rendered anonymous so that neither donors nor recipients remain identifiable. The data also include genetic information, collected within the scope of the Directive and to which third parties have access. In line with the Directive the Member States also have to ensure whilst guaranteeing the traceability of donations that (a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information; (b) procedures are in place to resolve data discrepancies; and (3) no unauthorised disclosure of information occurs.

8. SUPERVISION, COMPENSATION, PENALTIES

As it is mentioned before, according to Article 3 Sections (1)-(2) of the Human Blood and Transplants Act the Director General Health within the Ministry of Health is the Superintendent of Public Health which is operating as the licensing and supervisory authority in relation to the establishment and operation of tissue banks.

8.1. Ethical Committees[18]

In Malta the Bioethics Consultative Committee, the Health Ethics Committee, the Ethics Research Committee of Medical Teaching School at St Luke's Hospital, the Ethics Research Com-

[18] Information concerning the Bioethics Committees operating in Malta is based on the online database of the Privireal Project. Available at: http://www.privireal.org/content/rec/malta.php

mittee of the Institute of Health Care, the Ethics Subcommittee of the Faculty of Medicine and Surgery and finally the University Research Ethics Committee at the University of Malta are the six different ethics committees that are worth mentioning considering the establishment and management of biobanks and other related activities.

8.1.1. Bioethics Consultative Committee

The Bioethics Consultative Committee[19] (BCC) was established by the Ministry of Health in 1989 and it operates as an advisory body to the Ministry. The BCC's role in research is limited to formulating guidelines to be followed by various institutes and individuals, as well as to prepare opinions on ethical issues, publish articles, provide seminars and inform the public by means of pronouncing its views on questions relating to research ethics as the need arises. The BCC is also endeavour to sustain and encourage open discussion on bioethical issues. The Committee is not involved in the ethical assessment of individual research projects. The BCC is operated as a multidisciplinary body and its members come from medical, pharmacy, nursing, legal, ethical, and philosophical backgrounds and are appointed by the Minister for Health for the duration of one year on their own individual merit and capabilities. The Bioethics Consultative Committee has already adopted opinions on medically assisted procreation, on stem cell research; it also published opinions on advanced therapy medical products and on organ donation and transplantation as well. The next two future topics to be covered by BCC's opinions are the organ donation from anencephalic newborn infants and an opinion on the draft embryo protection Act.[20]

8.1.2. Health Ethics Committee

There is only one Ethical Committee operated in Malta, the Health Ethics Committee (HEC)[21] that has the power of approval on proceeding clinical trials.

The establishment of the HEC is under the remit of the Ministry of Health. As it is mentioned above the Ministry also appoints a Bioethics Consultative Committee, which is an advisory committee but which is not involved in the assessment of clinical trials. Therefore all clinical trials are at the sole responsibility of the HEC as established in the Clinical Trials Regulations. According to the Clinical Trials Guidance Notes[22] adopted by the Health Ethics Committee, the HEC is entitled to grant licence to commence clinical tri-

[19] Information on the current composition and members of the Bioethics Consultative Committee is available at: http://www.sahha.gov.mt/pages.aspx?page=67

[20] Reference to the opinions of the BCC is found in the Brochure of the European Commission on the International Dialogue on Bioethics Brussels, 19 February 2009. Available at http://ec.europa.eu/european_group_ethics/docs/brochure090219.pdf.

[21] Information on the Health Ethics Committee is available at: http://www.sahha.gov.mt/pages.aspx?page=134

[22] The Clinical Trials Guidance Notes is available at: http://www.sahha.gov.mt/showdoc.aspx?id=134&filesource=4&file=Guidancenotes_clinictrials.doc

als on medicinal products as per the Maltese Clinical Trials Regulations, 2004 (L.N. 490) and the European Clinical Trials Directive 2001/20/EC and to officially approve applications and grant licence to other clinical trials including those involving devices and interventions.

With reference to clinical trials, Article 7 of L.N. 490 of 2004 lays down that the Licensing Authority is entitled to set up an ethics committee which shall give its opinion, before a clinical trial commences, on any issue requested. The Ethics Committee provides its reasoned opinion to the applicant and the Licensing Authority within a maximum of sixty days from the date of receipt of a valid application. The HEC is also entitled to evaluate proposals for research being conducted in the health sector, including ethical and data protection aspects. The Health Ethics Committee is to carry out this responsibility in close collaboration with the Research Ethics Committee within the Faculty of Medicine and Surgery in the University of Malta and in line with the provisions of the Data Protection Act. The HEC is self-funding; fees charged for the review of clinical trials are used for administrative purposes. For example, office supplies, subscription to medical journals and the cost of obtaining the opinion of external experts during the assessment of clinical trials are paid for in this way. Members of the HEC receive no remuneration. Academic research without financial support from industry and clinical trials on orphan drugs may apply for reduced fees. Applicants conducting other clinical trials may also ask for reduced fees. Their requests will be evaluated on a case by case basis.

8.1.3. University Research Ethics Committee

The University Research Ethics Committee (UREC) at the University of Malta is also worth mentioning, with a special view to the 'University Guidelines'. The University Research Ethics Committee is established by the University Senate at the Medical School University of Malta. The UREC examines research projects of a biomedical nature submitted to it by anyone carrying out research involving humans at the University. Researchers however have no obligation to submit their project to this body. It reports to the Faculty of Medicine but has no authority to supervise the research projects it has authorised.

Guidelines for University Research Ethics Committee at UoM

The University Research Ethics Committee appointed in June 2002 set itself the task of drawing up a set of guidelines which were first approved in 2004 as 'Guidelines for UoM Research Ethics Committee', and reviewed by University Senate in September 2007. The guidelines envisage a simple structure that can safeguard both ethical standards and efficiency, while ensuring proper accountability. These guidelines were drawn up in close consultation with the Data Protection Commissioner's Office, who has ensured that they are in accordance with the Data Protection Act.

Submitting research proposals to the UREC is conducted on a voluntary basis, therefore although the approval of the University Ethics Committee of UoM is requested to commence research within the institutional framework of the

University, there are no consequences if the researchers fail to submit or fail to follow the review of the UREC. Nevertheless the REC at the University of Malta has to monitor all research it has approved and is entitled to halt the research in cases of non-compliance according to its guidelines (Section VI). In the case of non-compliance with the Guidelines the Dean and Senate of the University decide on sanctions to be taken.

Section V of the Guidelines also sets forth the provisions on the researchers' responsibility for obtaining informed consent in accordance with the guidelines and for ensuring that no human subject will be involved in the research prior to obtaining such consent.

Biological Resource Collection of the University of Malta

The University of Malta and the Department of Health established the Molecular Genetics Laboratory, in 1989. The initial priority of the laboratory was to set up a Genetic Testing program for Abnormal Heamoglobins and Thalassaemia, which later on expanded to include other conditions and a research programme on globin gene control. The Laboratory keeps a bank of 2000 DNA samples. It includes a random collection of cord blood DNA for population study purposes and DNA samples from patients with rare diseases. The Biological Resource Collection of the University of Malta consists of DNA and the number of available human samples are 2000 – including 200 control samples.

8.1.4. Other Ethics Committees

In addition to the above, further ethics committees also have to be mentioned with a view to the management of biobanks in Malta. While the Ethics Research Committee of the Medical Teaching School at St Luke's Hospital provides informal opinion and advice on the submitted research proposals at national level, the Ethics Subcommittee of the Faculty of Medicine and Surgery is concerned mainly with audit studies on patients in the public healthcare system.

The Ethics Research Committee of the Institute of Health Care is also worthwhile to note, which provides informal advice for researchers.

9. PUBLIC DEBATE

The establishment and service provision of a privately owned laboratory accredited in Malta has drawn the attention of the public to the legal and ethical aspects of the use of genetic information. The Bioethics Consultative Committee was consulted by the Maltese government on the amendment of the L.N. 21 of 1998 Industrial Development Act (Cap. 325) on Qualifying Export Services Companies (Maximum Rent Chargeable) Order, 1998 to make provisions for the above mentioned establishment to provide DNA sequencing services for non-residents in Malta[23].

[23] Beyleveld, Deryck: *Implementation of the Data Protection Directive in relation to medical research in Europe,* Ashgate Publishing, Ltd., 2004, 260.

II. FORENSIC BIOBANKS

1. DEFINITION OF FORENSIC BIOBANKS

Although there is no legal definition for forensic databases in Maltese legislation, according to current practice the police is entitled to collect any information of an evidential nature in the interest of criminal investigation. The Maltese Forensic Science Laboratory was set up in 1976. Malta has not established any specific legislation concerning forensic biobanks and the relevant legal regulation mainly consists of generally applied provisions of legal instruments in relation to taking samples and evidences in investigating procedures. It also has to be noted that although the Criminal Code sets out the main provisions in relation to the taking of intimate and non-intimate samples for forensic use by the police, the respective articles of the Criminal Code do not mention DNA or genetic tests explicitly as a way of obtaining evidence.

2. RELEVANT LAWS

The main legal regulations concerning forensic databases and the collection of genetic information in Malta can be categorized into two groups. Apart of the previously mentioned usage of genetic information in criminal investigations, certain methods of genetic testing and analysis on genetic information are also applicable in paternity cases[24].

According to Article 73 of the Police Act[25] the police may hold, process and classify any information relevant to the commission of any crime in or outside Malta. The Police Act also provides relevant provisions (Article 68-74) on the collection, management, processing and storage of evidences such as personal information in the interest of criminal investigation.

Furthermore Articles 355AV-355BC of the Criminal Code provide relevant information on investigative proce-

[24] Article 70 Section (1) (d) of the Civil Code sets forth the relevant provisions on proving paternity by means of genetic and scientific tests and data. According to the regulations of the Civil Code, if the alleged father proves that during the time in question the wife had committed adultery or that she had concealed the pregnancy and the birth of the child, and further produces evidence of any other fact (which may also be genetic and scientific tests and data) that tends to exclude such paternity.

[25] Ordinance II of 1961, Police Act (Cap. 164) To regulate the organization, discipline and duties of the Malta Police Force.. In original language: Att Dwar il-Pulizija, Kapitolu 164. Available at: http://docs.justice.gov.mt/lom/legislation/english/leg/vol_4/chapt164.pdf

dures in relation to the collection of evidences such as taking of samples, fingerprinting and other procedures.

Genetic information and other personal data based on genetic samples shall deem as sensitive personal data in line with Article 2 of the Data Protection Act. Nevertheless, Article 5 on the scope of the Data Protection Act, sets out that the Data Protection Act shall not apply to processing operations of personal data concerning public security, defence, state security (including the economic well being of the state when the processing operation relates to security matters) and activities of the state in areas of criminal law. Therefore the Minister responsible for data protection after consultation with the Data Protection Commissioner and with the concurrence of the Minister responsible for the police may by regulations make provisions extending the application of the Data Protection Act or adding to or derogating from the provisions mentioned above to enforce the provisions of any international obligation, convention or treaty relating to the protection of personal data, to which Malta is a party, or may become a party.

In line with the above mentioned provisions of the Data Protection Act, the subsidiary legislation, Legal Notice 142 of 2004, (Cap. 440.05) Data Protection Regulations on the processing of personal data in the police sector, entering into force on 30 September, 2004 is the significant legislative instrument in the respective domain. According to the L.N. 143 of 2004, the Data Protection Act shall be extended to apply to public bodies exercising police powers to the extent provided in the Regulations[26].

3. ESTABLISHMENT OF FORENSIC BIOBANKS

The establishment and maintenance of forensic biobanks (such as forensic laboratories and databases) are carried by the police on the basis of the Data Protection Act and related subsidiary legislations.

With view to the Police Act, Article 73 sets forth that the collection of information for the detection of crimes may relate to fingerprints, photographs measurements, blood-samples, intimate or non-intimate samples, patterns of criminal behaviours and methodology in the perpetration of an offence and similar details for the purposes of any future identification of offenders.

Article 350 of the Criminal Code provides that intimate sample means a sample of blood, semen or any other tissue fluid, or pubic hair, and includes a swab taken from a person's body orifice other than the mouth. The same article of the Code also sets forth that non-intimate sample means "a sample of hair other than pubic hair, a sample taken from a nail or from under a nail, a swab taken from any part of a person's body including the mouth but not any other body orifice, urine or saliva, a

[26] L.N. 142 of 2004, (Cap. 440.05) Data Protection Regulations (processing of personal data in the police sector) Available at: http://docs.justice.gov.mt/lom/Legislation/English/SubLeg/440/05.pdf

footprint or a similar impression of any part of a person's body other than a part of his hand."[27]

According to Article 4 of the Data Protection Regulation in the Police Sector the data controller (such as Commissioner of Police or his or her representative, or any other head of a public authority or body exercising police powers or his or her representative) shall notify the Commissioner for Data Protection where in the exercise of his or her duty, the controller is required to process personal data for police purposes. The notification shall cover the relevant information such as on the name and address of the controller and of any other person authorised by him or her in that behalf, if any, also the purpose or purposes of processing, a description of the category or categories of the data subject and of the data or categories of data relating to him or her.

According to Article 17 of the Data Protection Act, data relating to offences, criminal convictions or security measures may only be processed under the control of a public authority. For this purpose, the Minister responsible for data protection may by regulations authorise any person to process the data subject to such suitable specific safeguards as may be prescribed. The relevant provisions also set forth that a complete register of criminal conviction may only be kept under the control of a public authority.

4. SAMPLES AND SAMPLE TAKING, CONSENT

Data collection for police purposes covers the data samples that are managed and stored in forensic databases. According to the definition as laid down in the Data Protection Regulations in the Police Sector, 'police purposes' means all the tasks which the police (or other public entities, authorities or bodies exercising police powers) must perform for the prevention and suppression of criminal offences or the maintenance of public order.

According to the questionnaire[28] provided to the research the human biological samples collected and stored in forensic databases are various tissues, such as blood, saliva, etc. Forensic databases also include the personal data of the data subject, such as his or her name, sex, age and if relevant the database also contains the health data and criminal data of the data subject.

According to the current practice, the scope of collection is only limited to certain suspects depending on the degree of the potential charges, therefore the collection and analysis of the suspects' genetic information is solely applicable for the detection of serious crimes.

The samples are usually being collected when the suspect is taken in custody but only upon the written consent of the suspect. The Criminal Code differentiates between the procedures of taking intimate and non-intimate samples from arrested persons. Article

[27] Although it is disputed in the literature whether buccal swab taking is invasive or not, in the present analysis we do not take a position, just indicate the existence of the controversy.
[28] Information provided by Dr Bridget Ellul MB ChB, FRCPath, MRCPath, Histopathologist, Head University Department of Pathology, Senior Lecturer in Forensic Pathology.

355AV sets out that the investigating officer may submit a request to the Magistrate[29] to obtain authorization for processing certain procedures in relation to taking evidences from an arrested person. Upon the request of the investigating officer a Magistrate may authorise the taking of intimate samples from the person arrested but only if the request was reasonably grounded (Article 355AV Point (a)). In line with Article 355AW of the Criminal Code an intimate sample may be solely taken from a person arrested if his or her appropriate consent is given.

In case the arrested person withholds his or her consent, the Magistrate decides upon the request of the investigating officer, and declares whether the request is justified or not. Before making a decision, the Magistrate shall visit the person arrested to request his or her consent and the Magistrate is obliged to explain to him or her the nature of the request and the reasons thereof.

According to Article 355AV Point (b), the Magistrate's authorisation is also necessary to taking photographs, a film, video recording or electronic image of intimate parts of the arrested person's body. Furthermore the Magistrate can authorise any procedure if the arrested person refuses to cooperate with the police forces during the investigation (Article 355AV Point (c)).

It is also worth mentioning that according to the Article 355G of the Criminal Code the warrant of the Magistrate on taking evidences in the interest of the criminal investigation shall not extend to excluded materials such as human tissue or tissue fluid which have been taken for the purpose of diagnosis or medical treatment and which a person holds in confidence[30].

Article 355BA also sets forth that the person arrested may also request in writing the investigating officer to carry out any of the procedures mentioned in Article 355AV Points (a) and (b), in which case such request shall be referred to a Magistrate without delay.

With regard to sample taking from persons who are not in a custody, Article 355BB provides that samples may only be taken with that person's prior consent in writing and for the taking of an intimate sample a Magistrate's authorisation must also be obtained upon application.

Minors under nine years of age shall be exempt from criminal responsibility for any act or omission. Minors under fourteen years of age shall likewise be exempt from criminal responsibility for any act or omission done without mischievous discretion. On the contrary, Article 35 Section (3) sets out that the court on the application of the police may require the parent or other person charged with the upbringing of the minor to appear before it, and, if the fact alleged to have been committed by the minor is proved and is contemplated by the law as an offence, the court may oblige the parent or other person to watch over the conduct of the minor under penalty for noncompliance of a sum of not less than EUR 11.65 and not exceeding EUR 232.94 regard being had to the means of the

[29] Magistrate is a judge at the Court of Magistrates which is a court of criminal judicature.
[30] See also Professional Secrecy Act (Cap. 377).

person concerned and to the gravity of the fact. In case of an offence punishable with a fine (ammenda), the court may in lieu of applying the above mentioned provision, award the punishment against the parent or other person charged with the upbringing of the minor, if the fact could have been avoided by his or her diligence. Article 36 also sets out that minors under the age of fourteen but over nine who, acting with a mischievous discretion, commit an offence, shall be liable on conviction to the punishments established for contraventions of the law.

Considering the consent for taking sample from minors, Article 350 of the Criminal Code sets out that appropriate consent means in relation to a person who has not attained the age of eighteen but has attained the age of fourteen years, the consent of that person and the consent of his or her parent or guardian. Furthermore in relation to a person who has not attained the age of fourteen years, the consent of his or her parent or guardian is enough for collecting samples for criminal investigation. Nevertheless, it is also worth noting that according to Article 135 of the Civil Code the parents jointly represent their children, therefore both parents' consent is required for an appropriate consent.

Considering taking of samples from mentally disabled persons the Fourth Schedule of the Police Act is worth mentioning that sets forth a code of practice for interrogation of arrested persons. According to Article 17 Point (a) of Schedule IV as far as practicable, a mentally handicapped person shall be interviewed only in the presence of a parent, or his or her tutor or other person, not being a member of the police but who shall be for example the person providing effective care and custody of the handicapped person, or a social worker. With the view to the consent of a mentally disabled person to the collection of personal data or samples for criminal investigation, Article 17 Point(b) also lays down that any document reporting an interview with a mentally handicapped person (after the investigating officer shall have ascertained that the interviewed person was capable of making the statement) should be offered for signature not only to the handicapped person, but also to the mother or father or other accompanying person present during the interview.

5. PURPOSE AND SCOPE OF COLLECTION

According to Article 5 of the Data Protection Regulations in the Police Sector the collection of personal data for police purposes can be ordered when it is necessary for the prevention, suppression, investigation, detection and prosecution of specific criminal offences or for the prevention of real danger, or for other purposes specified by law. The above mentioned provision is in compliance with Article 23 of the Data Protection Act, which provides exemptions from the general provisions on data processing in the interest of national security, defence, public security, the prevention, investigation, detection and prosecution of criminal offences, or of breaches of ethics for regulated professions, an important economic or financial interest including monetary, budgetary and taxation

matters or a monitoring, inspection or regulatory function connected, even occasionally, with the exercise of an official authority in the field of public security, criminal or taxation investigations. Another exemption is also applicable when such information is being prejudicial to the protection of the data subject or of the rights and freedoms of others.

According to the questionnaire[31] provided for the research, the current practice covers forensic databases and biobanks for the purpose of identifying the suspect and victims of a crime, or databanks established in order to find an attested link between the suspect and the crime scene. Data collection also applies to the identification of refugees seeking asylum in Malta or the identification of deceased illegal immigrants.

The Data Protection Regulations in the Police Sector also lays down that when personal data are processed without the knowledge of the person concerned, the data subject should only be informed, where practicable, about the fact that information is held about him or her, as soon as the object of police activities is no longer likely to be prejudiced, and if the data have not been deleted. As it is mentioned before, genetic information is considered as sensitive personal data, therefore special provisions shall apply to the processing thereof. The processing of sensitive personal data is allowed if this is necessary for the purposes of a particular inquiry. Furthermore Article 6 of the Data Protection Regulation in the Police Sector also sets out that the processing of personal data for police purposes shall as far as possible, be limited to accurate data and to such data as are necessary to allow the public authority exercising police powers to perform their obligations as laid down in national legislation and to fulfil international obligations arising out of any convention, treaty or bilateral agreement relating to police matters to which Malta is a party. In relation to the purposes of the data collection the Regulation declares that collection of personal data for police purposes shall not be processed for any other purpose that is incompatible with such police purposes.

6. ACCESS TO DATA AND SAMPLES

Article 8 of the Data Protection Regulations in the Police Sector lays down the relevant provisions on the processing of personal data to third parties. According to the Regulations, communication of personal data between different bodies exercising police powers shall only be permitted where there exists a legitimate interest for such communication within the framework of the legal powers of such bodies. In addition to the above, personal data from bodies exercising police powers, to other Government Departments or to bodies established by law, or to other private parties may

[31] Information provided by Dr Bridget Ellul MB ChB, FRCPath, MRCPath, Histopathologist, Head University Department of Pathology, Senior Lecturer in Forensic Pathology.

only be transferred on the basis of a legal obligation or authorisation to process such data or if the Commissioner for Data Protection authorises such communication of data. Furthermore in exceptional cases data processing may also be carried out if it is clearly in the interest of the data subject and either the data subject him or herself has consented to the communication or circumstances are such as to allow a clear presumption of such consent or the data processing is necessary for the prevention of a serious and imminent danger. Article 8 Section (4) also declares that bodies exercising police powers may also communicate personal data to other Government Departments or bodies established by law, if the data are necessary for the recipient to enable him or her to fulfil his or her lawful task and provided that the purpose of the processing to be performed by the recipient is not incompatible with the original purpose of processing or contrary to the legal obligations of the body exercising police powers.

Nevertheless all the above mentioned data processing shall be made in compliance with Article 10 of the Regulations according to which the requests for communication of personal data shall be submitted in writing to the body exercising police powers, and shall include an indication of the person or body making the request and of the reason and purpose for which the request is made.

It also has to be mentioned that according to Article 12 of the Data Protection Regulation in the Police Sector in the course of executing their duties the body exercising police powers may have access to a personal data filing system held for purposes other than police purposes, in accordance with the law, provided that the other body who maintains the personal data filing system or the Data Protection Commissioner has authorised such access. With view to the aforementioned provisions of the law, the police is entitled to cross link the personal data information and samples stored in forensic databases with another database maintained by other authorities. This provision however has to be red in conjunction with the above mentioned Article 355G of the Criminal Code according to which the Magistrate's warrant on taking evidences in the interest of the criminal investigation shall not extend to materials such as human tissue or tissue fluid which have been taken for the purpose of diagnosis or medical treatment.[32]

Article 73 of the Police Act also sets forth that the police may, for the purpose of establishing evidence in the investigation into any criminal offence, compare any information (such as fingerprints, photographs, measurements, blood-samples, intimate or non-intimate samples, patterns of criminal behaviours and methodology in the perpetration of an offence and similar details) relevant to the commission of any crime

[32] See also Professional Secrecy Act (Cap. 377)

with any other information that may become available to it.

7. STORAGE

According to Article 73 of the Police Act, the information collected during the investigation process may be preserved by any system, including in electronic format, but in all cases the collection of data must be in compliance with the provisions of data protection regulations. Article 6 Sections (3)-(4) of the Data Protection Regulations in the Police Sector set forth that personal data processed for police purposes shall not be kept for a period longer than is necessary having regard to the police purposes for which they are processed.

The data controller shall take all reasonable measures to complete, correct, block or erase personal data to the extent that such data is incomplete or incorrect having regard to the police purposes for which they are processed.

In line with the Police Act, Article 554 of the Criminal Code also sets out that the Magistrate is entitled to order that any suspect be photographed or measured or that his or her fingerprints be taken or that any part of his or her body or clothing be examined during an inquiry by experts appointed by the Magistrate in the interest of the investigation. Provided that where the Magistrate is of the opinion that such photographs (negatives and prints), fingerprint impressions, records of measurements and any other potential evidence obtained from the body or clothing as aforesaid are no longer required for the purpose of the investigation, the Magistrate shall order their destruction or shall order that they be handed over to the person to whom they refer.

Considering the storage of personal data collected for police purposes, Article 68 of the Police Act lays down that any person may, within one year from the date of his or her acquittal by a final judgement of a court, demand that all samples, fingerprints and documents taken from him or her and any recordings of his or her voice or photographs or video recordings be returned to him or her or destroyed in the presence of the person. Such request of the data subject shall be made by application to a Magistrate who may authorize the request and in this case ensures that the material in question is returned to the data subject or destroyed in the presence of the Magistrate. Upon the decision of the Magistrate, the material in question is not returned to the data subject if is needed in connection with any other investigation. In such case the Magistrate may order that the return or destruction of any such material be detained until it is no longer required for the other investigation.

If the data subject is a person who has been arrested but not charged, the application may only be allowed if the police have already given their own reply to this application. The request of the data subject shall not be granted if it is opposed by the police and the period of prescription for the exercise of the criminal action in respect of the offence for which the applicant was arrested and convicted has not lapsed (Article 71).

Article 72 of the Police Act provides, that where the person acquitted or the

person arrested but not charged fails to submit a request to a Magistrate, the police may transfer any and all evidences or samples and so forth to the Police Academy if the material is considered by the police to have a didactic or experimental value.

Article 73 also states that the police may hold, process and classify any information relevant to the commission of any crime in or outside Malta which information may be preserved by any system whatsoever, including in electronic format, subject to the provisions of any law on the protection of data. Such information may relate to fingerprints, photographs, measurements, blood-samples, intimate or non-intimate samples, patterns of criminal behaviours and methodology in the perpetration of an offence and similar details for the purposes of any future identification of offenders.


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