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L.N. 300 of 2024

HEALTH ACT
(CAP. 528)

Functions and Responsibilities of the Department operating the Blood, Tissue and Cells Centre Regulations, 2024

IN EXERCISE of the powers conferred by article 30 of the Health Act, the Minister responsible for health, has made the following regulations:-

1. The title of these regulations is the Functions and Responsibilities of the Department operating the Blood, Tissue and Cells Centre Regulations, 2024. Citation.

2. (1) In these regulations, unless the context otherwise requires: Interpretation.

"Act" means the Health Act; Cap. 528.

"blood" means whole blood collected from a donor and processed either for transfusion or for further manufacturing;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue;

"Centre" means the Blood, Tissue and Cells Centre, an establishment for the collection, processing, storage and distribution of blood, tissues and cells;

"data subject" means any individual whose personal data is being collected, held or processed;

"Department" means the Department operating the Blood, Tissue and Cells Centre established by the Act to develop and to operate the Centre for the reception, collection, processing, storage and distribution of blood, tissues and cells and to perform other functions or responsibilities entrusted to it by law;

"Regulation (EU) 2016/679" means 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 (General Data Protection Regulation);

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"tissue" means all constituent parts of the human body formed by cells.

(2) Words and expressions used in these regulations shall have the same meaning as assigned to them in the Act.

Functions and responsibilities of the Department.

3. (1) It shall be the function of the Department in general to develop and to operate the Centre for the reception, collection, processing, storage and distribution of blood, tissues and cells.

(2) In particular, the functions and duties of the Department shall include:

(a) to provide blood banking services, including labile blood products, stem cell collection for cellular therapies, including autologous stem cell transplantation, human leukocyte antigen typing, bone marrow donor registry, and tissue banking services including bone, cornea and amnion banking services and any other tissues and cells for which there is clinical demand;

(b) to participate in research, innovation, training and education activities through partnerships with appropriate bodies;

(c) to advise the Government on issues related to the core functions of the Centre;

(d) to promote research, teaching and training in the fields relating to its functions and responsibilities;

(e) to cooperate with local and international organisations on matters relating to its functions and responsibilities;

(f) to advise upon innovative models of service provision and delivery following consultation, where necessary, with relevant stakeholders;

(g) to anticipate the needs of professional staff, and other human resources, and to collaborate with third parties, including the University of Malta established in accordance with article 72 of the Education Act, the Malta College of Arts, Science and Technology established and incorporated in accordance with article 86 of the Education Act and any other institutions, public and private, in order to ensure the training and development of healthcare professionals and non-healthcare personnel, according to their needs in matters relating to the functions and responsibilities of the Department;

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(h) to carry out such other function or functions as the Minister may from time to time determine and direct; and

(i) to implement any other matter required for the fulfilment of its mission, and for the execution of duties pertaining to the State, as established in the Act.

Data protection. Cap. 586.

4. (1) Nothing in these regulations shall prejudice the applicability of Regulation 2016/679/EC and the Data Protection Act, including the regulations made thereunder, and the fundamental rights and freedoms of the data subjects.

(2) The Department in its capacity of a controller in terms of Article 4(7) of Regulation (EU) 2016/679 shall perform the relevant data processing operations which are limited to the extent necessary and proportionate to perform its functions and duties.

(3) Any personal data processed by the Department shall fully comply with all the principles relating to the processing of personal data pursuant to Article 5 of Regulation 2016/679/EC.

(4) The Department, whilst taking into account the nature, scope, context and purpose of processing, as well as the risks of varying likelihood and severity for the rights and freedoms of the data subjects, shall implement appropriate technical and organisational measures, in an effective manner in order to ensure a level of security appropriate to the risks.

(5) For the purpose of ensuring and to be able to prove compliance with the principles relating to the processing of personal data, the Department shall implement appropriate data protection policies, which policies shall be reviewed and updated where necessary.

(6) The access to personal data shall be reserved exclusively to duly designated officers on the basis of a role-based access control mechanism and subject to confidentiality and, or professional secrecy obligations, in order to prevent abuse or unlawful access to, or disclosure of personal data.

(7) The data protection officer designated by the Department in terms of Article 37 of Regulation 2016/679/EC shall be involved and duly consulted and in a timely manner in relation to the protection of personal data processed for the purpose of these regulations.

National Health Service.

5. The activities and services offered by the Department and the Centre are an integral part and inseparably connected with the public healthcare system, and are part of the State's social and

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healthcare obligations.

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