

Order for Enforcement of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field

(Cabinet Order No. 163 of May 7, 2018)

The Cabinet hereby enacts this Cabinet Order pursuant to the provisions of Article 2, paragraphs (1), (4), and (5), Article 8, paragraph (3), item (i), (a) and (c), 3. (including as these provisions are applied mutatis mutandis pursuant to Article 29), Article 16, paragraph (3) (including as applied mutatis mutandis pursuant to Article 29), and Article 30, paragraph (1) of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (Act No. 28 of 2017).

(Medical Information)

Article 1 The descriptions and accounts specified by Cabinet Order that are referred to in Article 2, paragraph (1) of the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (hereinafter referred to as the "Act") mean the following:

- (i) the medical history of a specific individual;
- (ii) a description or account containing any of the following information (other than a description or account also falling under the preceding item):
 - (a) the fact that the person in question has a physical disability, intellectual disability, mental disability (inclusive of developmental disabilities), or other impairment of physical or mental function specified by Order of the competent ministries;
 - (b) the results of a medical check-up or other examination (referred to as a "medical check-up or examination" in (c)) for the prevention and early detection of diseases that has been conducted on a specific individual by a medical doctor or other person engaged in duties relevant to medicine (referred to as a "doctor or other medical professional" in (c)); and
 - (c) the fact that, based on the results of a medical check-up or examination or due to a disease, injury, or other mental or physical change, a specific individual has been provided with guidance that is meant to improve the individual's mental or physical condition, or with medical care or a prescription, by a doctor or other medical professional.

(Databases and Similar Collections of Anonymized Medical Data)

Article 2 That which is specified by Cabinet Order as referred to in Article 2, paragraph (4) of the Act means a collection of information that has been

systematically organized by arranging anonymized medical data contained in that collection according to established rules that enable a person to readily search for specific anonymized medical data, and that has a table of contents, index, or the like to facilitate searches.

(Databases and Similar Collections of Medical Information)

Article 3 (1) That which is specified by Cabinet Order as referred to in Article 2, paragraph (5) of the Act means a collection of information that has been systematically organized by arranging medical information contained in that collection according to established rules that enable a person to readily search for specific medical information, and that has a table of contents, index, or the like to facilitate searches.

(Acts Specified by Cabinet Order That Are Referred to in Article 8, Paragraph (3), Item (i), (a) and (c), 3. of the Act)

Article 4 The Acts specified by Cabinet Order that are referred to in Article 8, paragraph (3), item (i), (a) and (c), 3. of the Act (including as applied *mutatis mutandis* pursuant to Article 29 of the Act) are as follows:

- (i) the Act on the Protection of Personal Information (Act No. 57 of 2003);
- (ii) the Act on the Protection of Personal Information Held by Administrative Organs (Act No. 58 of 2003);
- (iii) the Act on the Protection of Personal Information Held by Incorporated Administrative Agencies (Act No. 59 of 2003); and
- (iv) the Act on the Use of Numbers to Identify a Specific Individual in Administrative Procedures (Act No. 27 of 2013).

(Bearing of Costs Required to Undertake Inspections at the Offices of Foreign Handlers)

Article 5 The costs specified by Cabinet Order that are referred to in Article 16, paragraph (3) of the Act (including as applied *mutatis mutandis* pursuant to Article 29 of the Act) are those constituting the amount of travel expenses needed in order for the officials referred to in Article 16, paragraph (1), item (iii) of the Act (including as applied *mutatis mutandis* pursuant to Article 29 of the Act) to take a business trip to the locality of an office or other place of business subject to inspection under that item (limited to one that is located in a foreign state) for the purpose of that inspection. In such a case, Order of the competent ministries provides for the necessary details regarding the calculation of the amount of those travel expenses.

(Scope of Surviving Family)

Article 6 The persons specified by Cabinet Order that are referred to in Article

30, paragraph (1) of the Act mean the deceased principal's spouse (inclusive of a person whose involvement with the deceased principal was the same as a marital relationship for all practical purposes, even though no marriage had been registered), children, parents, grandchildren, grandparents, and siblings.