

APLAW Artur Piechocki
Wał Zawadowski 93a / 2
02-986 Warszawa
+48 606 294 306
artur.piechocki@aplaw.pl
www.aplaw.pl



Warsaw, 27 June 2022

Dear Ms. President

Ligia Kornowska Najbuk

Foundation "Podaruj Dane", based in Warsaw

Żelazna street 59 /1405, 00-848 Warsaw

LEGAL OPINION

**on the lawfulness of a data subject's statement of consent to the processing of personal data
("Opinion")**

Grounds and purpose of preparing the Opinion

The following Opinion has been prepared at the request of Podaruj Dane Foundation with its registered seat in Warsaw (hereinafter referred to as: the Foundation). The legal issue presented for an opinion concerns the determination if:

Does the content of the consent for the processing of personal data presented below complies with the provisions of 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) (EU. L. 2016 No. 119, p. 1 as amended)?

The data donor's consent to the processing of his/her personal data to enable scientific research and research and development work in medical science by the Podaruj Dane Foundation:

I consent to the processing of my personal data by the Podaruj Dane Foundation:

- a) name, surname,
- b) PESEL number,
- c) telephone number, e-mail address,
- d) data included in medical records kept by entities performing medical activities in Poland and in other countries, in particular data concerning health condition,
- e) health data from the repositories of public entities that do not provide medical services, if these entities allow access to the personal data indicated,
- f) health data from repositories of non-public entities that are not health care providers, if those entities allow access to the personal data indicated,

- g) data describing the sample biological material and the biological material itself (if I have given separate consent for the release of the biological material),
- h) genetic data about inherited or acquired genetic characteristics,
- i) health data that I will make available through a data donor account provided directly by me, information about clinical trials and other medical experiments in which I have participated or will participate and for which I will be qualified; as well as information generated in the course of these trials.

Whereby consent applies both to data currently in existence as well as data created up to the date of my withdrawal of consent. For further, detailed information on the scope of the data processed and the principles of processing, please see the following information on the principles of processing personal data of the data donor.

I give my consent in order to enable the Podaruj Dane Foundation to carry out its activities for the benefit of scientific research and research and development in medical sciences through the processing, including completing and anonymizing of personal data by the Podaruj Dane Foundation.

Conclusions

- I. The legal grounds for data processing, on which the facts analysed in this Opinion were based, is the consent of the natural person referred to in Article 9(2)(a) of the GDPR.**
- II. The content of the consent, as well as the manner in which it is obtained, complies with the provisions of the GDPR, as well as with the guidelines issued by authorized bodies, such as the European Data Protection Board. The consent meets the conditions required to be considered voluntary, specific, informed, unambiguous and, above all, express.**
- III. In view of the above, it must be assumed that the processing of health data of an individual (i.e. the data donor) has a valid legal basis in the form of the data subject's consent.**
- IV. Consent is a valid basis for the processing of personal data contained in medical records, located in public repositories, from public as well as private entities and from the data subjects themselves.**

Facts

The factual state to which the Opinion relates has been established on the basis of information received from the Podararuj Dane Foundation, in particular the draft consent of the data donor to the processing of his/her personal data in order to enable scientific research and research and development work in medical sciences by the Podararuj Dane Foundation.

Legal Acts, judgments and materials on which the Opinion is based

1. 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) (EU OJ L. 2016 No. 119, p. 1 as amended), in short: **GDPR**;
2. European Data Protection Board Guidelines 05/2020, adopted on May 4, 2020, in short: **Guidelines 05/2020**;
3. M. Kuba [in:] GDPR. General Regulation on Data Protection. Commentary, ed. E. Bielak-Jomaa, D. Lubasz, Warsaw 2018, art. 9. <https://sip.lex.pl/#/commentary/587747150/544590/bielak-jomaa-edyta-red-lubasz-dominik-red-rodo-ogolne-rozporzadzenie-o-ochronie-danych-komentarz?cm=URELATIONS> (access: 2022-06-20 11:11);
4. P. Fajgielski [in:] Commentary to Regulation 2016/679 on the protection of individuals 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) [in. Personal Data Protection Act. Commentary, 2nd edition, Warsaw 2022, art. 9. <https://sip.lex.pl/#/commentary/587773153/670981/fajgielski-pawel-komentarz-do-rozporzadzenia-nr-2016-679-w-sprawie-ochrony-osob-fizycznych-w...?cm=URELATIONS> (access: 2022-06-20 11:12).

1. Processing of ordinary data on the basis of the data subject's consent

It should be noted that apart from the issues strictly related to the processing of special categories of data (i.e. health-related data), the content of the consent also covers the data subject's consent to the processing of his/her ordinary data (i.e. identification data, such as name, surname, pesel, address of residence, data in medical records which are not classified as health-related information). The obtaining and processing of this information, from the data controller's point of view, is necessary for the proper identification of the data subject. In addition, information such as the address of residence will be included in medical records, which may be in the form of paper documentation. Some of the mentioned information will be obtained by the Foundation from the data subject at an earlier stage, i.e. during account registration in the electronic data donation system. These data will be provided by the data subject for a purpose not directly related to the donation process, but to the conclusion and performance of a contract for the provision of electronic services, as the basis for the processing of personal data. A separate legal basis is therefore required for the processing of these data at the stage of the data donation process. The content of Article 6(1)(a) of the GDPR provides for the possibility of basing the processing of personal data in such a process on the consent expressed by the data subject.

2. the lawfulness of processing health information

According to the definition contained in Article 4(1) GDPR, personal data shall mean any information relating to an identified or identifiable natural person, whereby an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the natural person.

In addition, according to the content of Article 4(15) of the GDPR, personal data about the physical or mental health of an individual should be classified as health data. This category of data also includes information about the use of healthcare services that reveal information about the health of an individual.

The processing of data concerning the health of an individual is prohibited in principle under the GDPR (Article 9(1) GDPR). However, the prohibition is not absolute. The processing of data concerning health is possible if there are reasons that legitimise the processing, as indicated in Article 9(2) GDPR. One of the permissible prerequisites is the consent given by the natural person (i.e. data subject) to the processing of information about his/her health (Article 9(2)(a) GDPR).

In addition, consent should be given explicitly, as well as for one or more specific purposes of processing. In the context of point 1 of the Opinion, in the case of consent to the processing of special categories of data, the prerequisites for the admissibility of the processing of so-called ordinary data also remain valid¹.

3. Meeting the conditions for consent to process health data

a) Freely given consent

In the case of the analyzed content of the consent, **the condition of the freely given consent must be deemed to be met**. According to the position of the European Data Protection Board, with regard to the processing of personal data, the feature of "freely given" consent implies the actual possibility of choice and control by the data subjects. The data subject (data donor) independently decides whether to join a data donation program and whether to allow his or her health data to be processed. It goes without saying that the data donor is given a real choice. In particular, the data subject will not suffer any negative consequences if he or she does not give consent, nor is giving consent an inherent and non-negotiable part of the terms of the contract. The data subject may refuse consent, as well as declare the withdrawal of consent at any time.

It should also be noted that the data subject does not have any relationship with the Foundation (i.e. the data controller) that could be assessed as a subordinate relationship that would influence the data subject's decision-making process. In the analyzed case, no pressure of any kind is exerted on the data donor or any other type of undue influence. There will be no imbalance of power in the case under analysis, as the Foundation is not a public authority, nor is it the data subject's employer.

Also, giving consent is not a condition for concluding a contract (including a contract for the provision of services by electronic means), or for providing a service to the data subject. In particular, the purpose of processing personal data is not hidden, let alone linked to the performance of a contract or the provision of a service. It is true that under the donation system it is possible to receive a "token" linked to a benefit, however, this requires the donor to enter into a separate contract. The possibility of obtaining a 'token' is therefore not conditional on giving consent. The act of giving consent does not constitute either a direct or an indirect consideration for the performance of the contract.

b) Specificity

¹ P. Fajgielski [in:] Commentary to Regulation 2016/679 on the protection of individuals 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) [in:] Personal Data Protection Act. Commentary, 2nd edition, Warsaw 2022, art. 9.

As required by the GDPR and guidelines adopted by the European Data Protection Board, the data subject must give consent "for one or more specified purposes." In addition, the data subject is given a choice with respect to each of the purposes. It is pointed out that the requirement of "specificity" of consent is intended to ensure a certain degree of user control and transparency with respect to the data subject².

It should be noted that according to the guidelines³ the "specificity" requirement for consent should be considered satisfied where the controller:

- specifies the purpose for which consent is sought;;
- provides details in reply to requests for consent;
- clearly separates information related to obtaining consent for processing activities from information on other topics.

The content of **the consent referred to in the Opinion meets the condition of specificity. In the case under analysis**, the abovementioned conditions are deemed to be met, as firstly the purpose of personal data processing to which the consent relates has been specified. The purpose identified by the data controller should be assessed as specific and detailed. The controller indicated that the consent concerns the processing of personal data for the purposes of scientific research and research and development in medical sciences. Second, the possible processing operations were indicated and the types of data that will be processed as part of the process covered by the consent were described.

It should be noted that the requirement is for the data subject to give consent "for one or more specified purposes". In addition, the data subject is given a choice with respect to each of the purposes⁴. In each separate request for consent, controllers should provide details of the data that are being processed for each purpose, in order to make data subjects aware of the implications of the different choices they may make⁵. As also explicitly indicated in the GDPR, consent should apply to all processing activities carried out for the same purpose or purposes. If the processing serves different purposes, consent is needed for all those purposes⁶.

The above conditions may be deemed met, especially as the content of the consent does not raise any doubts as to its specificity. Consent relates to a single, precisely defined purpose. Additionally, consent may cover various processing operations, provided that these operations serve the same purpose⁷. In the opinion of the opinionator, the controller has ensured that the processing operations serve the purpose of conducting scientific research and research and development in medical science. Therefore, it is not necessary to obtain separate consents of the data subject for individual operations.

c) Informed consent

Compliance with the information obligation is necessary to enable the data subject to make an informed decision, to understand what they are consenting to, and to exercise their right to withdraw consent.

² Guidelines 05/2020, p. 14.

³ Guidelines 05/2020, p. 15.

⁴ Guidelines 05/2020, p. 14.

⁵ Guidelines 05/2020, p. 16.

⁶ Recital 32 GDPR.

⁷ Guidelines 05/2020, p. 15.

In order to obtain informed consent, the data subject must be informed of certain key elements in order to make a choice. In accordance with accepted guidelines ⁸, in order to obtain valid consent, it is required to provide the data subject with at least the following information:

- the identity of the controller;
- the purpose of each processing operation for which consent is sought;
- the type of data that will be collected and used;
- where applicable, the existence of the right to withdraw consent; the use of data for automated decision-making purposes in accordance with Article 22(2)(c) of the GDPR;
- where applicable, about the possible risks of data transfers in the absence of an adequacy decision and appropriate safeguards in accordance with Article 46 of the GDPR.

If the required information is not provided to the data subject, the consent cannot be considered informed. Such a situation does not occur in the case under review.

In the case under analysis, the data subject gives informed consent. First of all, the data subject is provided with access to the necessary and required by the GDPR information, which the data subject has the opportunity to read before giving consent. Consent is obtained prior to the processing of personal data for a specific purpose.

It should also be noted that the content of the information obligation has been formulated in simple, clear language in order to make the content easy to understand for the average recipient. The request is clear and concise. The content of the consent as well as the content of the information obligation is a separate document, i.e. it has been separated from the privacy policy.

d) Unambiguous consent

It is assumed that consent should be given by means of an unambiguous affirmative act which expresses, with regard to a given situation, the data subject's freely given, informed and unambiguous consent to the processing of personal data relating to them⁹. Thus, consent must always be given by an active action or statement. It must be obvious that the data subject has consented to a particular processing ¹⁰.

In the analyzed case, **the consent should be assessed as unambiguous**, because the data subject performs a specific, confirmatory action in the form of choosing the appropriate "checkbox" and then confirms the choice. Acquiring the consent requires a separate action. The consent option box is not checked by default, so the consent requires an action by the data subject. Consent is not obtained by the same action as concluding a contract or accepting general terms and conditions of service.

e) Explicit consent

Significantly, Article 9(2)(a) of the GDPR requires that consent to the processing of sensitive data, in addition to meeting the general requirements, must be "explicit consent" ¹¹. The term "explicit" refers to the manner in which the data subject gives consent. This means that the data subject must make a

⁸ Guidelines 05/2020, p. 16-17.

⁹ Recital 32 GDPR.

¹⁰ Guidelines 05/2020, p. 19.

¹¹ P. Fajgielski [in:] Commentary to Regulation 2016/679 on the protection of individuals 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) [in: Personal Data Protection Act. Commentary, 2nd edition, Warsaw 2022, art. 9.

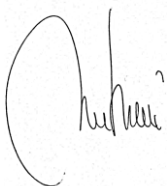
statement of consent in an active manner¹². Therefore, there can be no effective consent to the processing of special categories of data by implication, since the legislator requires in this case an explicit statement¹³. The legislator in this case requires a clear affirmative action, which means that the data subject must take a deliberate action to consent to a specific processing¹⁴.

In the case analysed in the Opinion, **the consent given by the data subject should be assessed as explicit**. It should be noted that the data subject is giving his/her will in a concrete way, in the form of an explicit affirmative action. The manner in which the consent is given is irrelevant, since, according to the guidelines, in a digital or online environment, the data subject may be able to make the required valid and explicit declaration by, for example, filling in an electronic form, sending an e-mail message, sending a scanned document bearing the signature of the data subject, or affixing an electronic signature.¹⁵ As the GDPR indicates, where a data subject is required to provide consent in response to an electronic request, such request should be clear, concise and not unnecessarily interfere with the use of the service to which it relates¹⁶.

In the case under analysis, the data subject's behaviour, aimed at giving consent, consists of an independent, active action in the form of ticking the appropriate "checkbox". Moreover, the data subject takes additional actions in order to pass the verification required by the operator of the data donation system. The ability to give consent in the data donation process is also preceded by user account registration and identity verification by a trusted third party. Thus, the data subject must undertake some effort and actions before submitting the consent statement, which shows that the data subject is determined to participate in the donation process and provide consent. The consent query does not interfere with the use of the e-service itself, as it occurs at a stage after the user has started using the e-service.

4. The ability to obtain data based on consent

It should be assumed that the consent given by the data subject (the data donor) is a valid basis for the processing of personal data contained in medical records, located in public repositories, from public as well as private entities and from the data subject himself. On this basis, as well as on the basis of the data subject's properly granted authorization to access health data and medical records, the Foundation may obtain and subsequently process personal data, in accordance with the purpose covered by the data subject's consent.



Artur Piechocki – Legal advisor

¹² Guidelines 05/2020, p. 19.

¹³ P. Fajgielski [in:] Commentary to Regulation 2016/679 on the protection of individuals 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) [in: Personal Data Protection Act. Commentary, 2nd edition, Warsaw 2022, art. 9.

¹⁴ Guidelines 05/2020, p. 19.

¹⁵ Guidelines 05/2020, p. 22-23.

¹⁶ Recital 32 GDPR.