

The exceptions for processing special categories of personal data in the context of scientific or historical research

Participatory evaluation

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Questions of research

1. Are there any national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?
 2. Are there any national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?
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Austria

Are there national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

If it is a processing for archiving purposes in the public interest, **scientific** or historical **research purposes** or statistical purposes and whose goal is **not to obtain person-related results**, then Paragraph (7)(2) of the Austrian Data Protection Act (Datenschutzgesetz – DSG) applies.

In this case, corresponding data processing operations, including personal data, may only take place pursuant to specific legal provisions, with the consent of the data subject, or with a permit of the Data protection Authority.

The permit of the Data Protection Authority for the processing of personal data regarding the aforementioned kind of purposes shall be granted at the request of the controller ordering the research project, if the consent of the data subject is impossible to obtain because the data subject cannot be reached or the effort would otherwise be unreasonable, there is a public interest in the processing for which a permit is sought and the professional aptitude of the controller has been satisfactorily demonstrated.

In addition, if special categories of personal data according to Article 9 of the GDPR are to be collected, an important public interest in the research project must exist, furthermore, it must be ensured that the personal data are processed at the premises of the controller ordering the research project only by persons who are subject to a statutory obligation of confidentiality regarding the subject matter of the research project or whose reliability in this respect is credible. The Data Protection Authority shall issue the permit subject to terms and conditions, insofar as this is necessary to safeguard the data subjects' interests which deserve protection.

The respective request must, however, be accompanied by a statement signed by the person authorised to exercise rights in respect of the data files from which the personal data are to be collected, stating that this person is making the data files available for the research project.

Are there national derogations from the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

The DSG itself does not contain any derogations with regard to the rights of data subjects within the context of scientific research. However, the Austrian legislator has made use of this option in Article 2d (6) of the Research Organization Act (Forschungsorganisationsgesetz – FOG).

Accordingly, the following rights of data subjects are not applicable if the scientific research purpose is likely to be made impossible or seriously impaired by the assertion of such rights of data subjects:

- Right of access (Article 15);
- Right to rectification (Article 16);
- Right to erasure ('right to be forgotten') (Article 17);
- Right to restriction of processing (Article 18);
- Right to data portability (Article 20);
- Right to object (Article 21);

Also noteworthy is the regulation according to Paragraph 2d (7) of the FOG, according to which, on the basis of Article 9(2)(j) of the GDPR within the meaning of Paragraph (7)(2) DSG, it is not necessary to obtain an authorisation from the data protection authority if special categories of personal data are to be processed, if the processing takes place in accordance with the regulations of the FOG.

Bulgaria

Are there national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

Personal data, including special personal data, initially collected for another purpose, may be processed in the context of scientific research. In the last case the controller must apply appropriate technical and organizational measures that safeguard the rights and freedoms of the data subjects in compliance with Article 89(1) of the GDPR.

Are there national derogations from the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

No derogations are envisaged.

Czech Republic

At that time, we were still optimistic that the Czech draft Law on personal data processing will be passed by the Parliament by the end of February. However, the Senate has sent back the draft Law to the National Assembly and its next session is scheduled for mid-March.

Nevertheless, we believe that the draft will not be changed significantly from its latest version, therefore we provide you with the answers to your questions, noting that the Law is yet to be adopted.

Are there national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

Czech draft Law on personal data processing states that the personal data controller and/or processor that processes special categories of personal data for scientific research shall conduct anonymization of such personal data, unless it hampers the achievement of the purpose for which this data is being processed. The anonymization shall not be conducted provided it is against the legitimate interest of the data subject.

The draft Law also provides a list of obligations for each data controller/processor that processes any type of personal data for scientific research, including an obligation to take adequate technical and organisation measures to limit the scope of the personal data processed, to appoint a data protection officer, to encrypt the data and limit the access of the controller's/processor's personnel to it.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(3) of the GDPR)?

Yes, the draft Law provides a special regulation for the implementation of data subject's:

- right of access,
- right to rectification,
- right to restriction of processing, and
- right to object the processing.

The draft Law stipulates that the regulation of these rights included in the GDPR shall be used „proportionately“ or the realisation of these rights shall be postponed if it is necessary and proportionate to the achievement of the purpose for which this data is being processed, i.e. the scientific research.

Denmark

Are there national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

Section 10 of the Danish Data Protection Act (DDPA) is the implementation of the derogation in article 9(2)(j). Section 10 of the DDPA permits processing of special personal data for the sole purpose of carrying out scientific studies of significant importance to society and where such processing is necessary in order to carry out these studies.

The data covered by Section 10 (article 9) may only be disclosed to a third party with prior authorization from the Danish Data Protection Agency when such disclosure:

1. is made for the purpose of processing outside the territorial scope of the General Data Protection Regulation, see Article 3 of the General Data Protection Regulation;
2. relates to biological material; or
3. is made for the purpose of publication in a recognized scientific journal or similar.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

According to section 22(5) of the Danish Data Protection Act, GDPR article 15 (right of access by the data subject), 16 (right to rectification), 18 (right to restriction of processing) and 21 (right to object) do not apply if the data is solely processed for scientific or statistical purposes.

Finland

Are there national exceptions in your member state for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

If this refers to exceptions made to the prohibition under GDPR 9(1), as allowed under Article 9(2)(j) based on national law, then yes. Section 6 of the Data Protection Act (1050/2018) includes the general implementation in this regard, but more specific stipulations may also be provided under special legislation. We have not charted such possible special statutes concerning scientific research. If any, they would likely be limited to very specific research purposes, e.g. in relation to a particular field or activity.

Under Section 6 of the Data Protection Act, the prohibition of processing special category data (GDPR 9(1)) data is not applied where, inter alia, the processing is carried out for scientific or historical research purposes or statistical purposes.

In accordance with the same Section, when processing special category data for such purposes, controllers and processors must carry out suitable and specific measures to safeguard the rights of the data subject, including inter alia as appropriate:

- 1) measures providing for an *ex post* possibility to ensure and verify who has saved, modified or transferred the personal data;
- 2) measures to improve the competences of the personnel processing the personal data;
- 3) appointing a data protection officer;
- 4) internal measures of the controller and the processor to restrict access to the personal data;
- 5) pseudonymization of the personal data;
- 6) encryption of the personal data;
- 7) measures to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services, including the ability to restore the availability and access to the personal data in a timely manner in the event of a physical or technical incident;
- 8) a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;
- 9) specific rules of procedure to ensure compliance with the General Data Protection Regulation and this Act when transferring the personal data or processing it for another purpose;
- 10) carrying out a data protection impact assessment referred to in Article 35 of the General Data Protection Regulation;
- 11) other technical, procedural and organisational measures.

It is the responsibility of the relevant controller and/or processor to assess which of these measures, if any, are appropriate in relation to the processing carried out.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

Yes, there are national derogations in the context of Article 89(2) of the GDPR. Section 31(1) of the Data Protection Act sets out the following:

“When processing personal data in scientific or historical research purposes, the rights of the data subject under Articles 15, 16, 18 and 21 of the General Data Protection Regulation may be derogated from provided that:

- 1) the processing is based on an appropriate research plan;
- 2) a person or a group of persons responsible for the research have been designated; and

- 3) the personal data is used and disclosed solely for purposes of historical or scientific research or other compatible purpose, and the procedure followed is also otherwise such that data pertaining to a given individual is not disclosed to outsiders.”

Germany

Are there national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9 (2) (j) of the GDPR)?

- In Germany, processing of special personal data in the context of scientific research with regard to Article 9 (2) (j) GDPR is addressed in Para. 27 German Federal Data Protection Act (please see **annex** below).
- The term “scientific research” should be interpreted in a broad manner.
- The term encompasses "everything that can be considered in content and form as a serious, planned attempt to ascertain the truth."
- There is no limitation to certain areas and/or specific institutes.
- However, the context of scientific research does not cover research regarding marketing and opinion purposes. Commercial studies, for example, which the marketing department of a company itself or a private opinion research institute on behalf of a company performs, and in the simple application of methodological guidelines to specific circumstances, are not covered by Para. 27 German Federal Data Protection Act. In contrast, the market analysis of an independent research institute may be included in the concept of scientific research, provided that it generates new insights.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?”

- As far as we can tell, in Germany there is no derogation to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR).
- The relevant wording of the GDPR has been copied into Para. 27 German Federal Data Protection Act (please see **annex** below).

Annex

Section 27 German Federal Data Protection Act

Data processing for purposes of scientific or historical research and for statistical purposes

(1) By derogation from Article 9 (1) of Regulation (EU) 2016/679, the processing of special categories of personal data as referred to in Article 9 (1) of Regulation (EU) 2016/679 shall be permitted also without consent for scientific or historical research purposes or statistical purposes, if such processing is necessary for these purposes and the interests of the controller in processing substantially outweigh those of the data subject in not processing the data. The controller shall take appropriate and specific measures to safeguard the interests of the data subject in accordance with Section 22 (2), second sentence.

(2) The rights of data subjects provided in Articles 15, 16, 18 and 21 of Regulation (EU) 2016/679 shall be limited to the extent that these rights are likely to render impossible or seriously impair the achievement of the research or statistical purposes, and such limits are necessary for the fulfilment of the research or statistical purposes. Further, the right of access according to Article 15 of Regulation (EU) 2016/679 shall not apply if the data are necessary for purposes of scientific research and the provision of information would involve disproportionate effort.

(3) In addition to the measures listed in Section 22 (2), special categories of personal data as referred to in Article 9 (1) of Regulation (EU) 2016/679 processed for scientific or historical research purposes or statistical purposes shall be rendered anonymous as soon as the research or statistical purpose allows, unless this conflicts with legitimate interests of the data subject. Until such time, the characteristics enabling information concerning personal or material circumstances to be attributed to an identified or identifiable individual shall be stored separately. They may be combined with the information only to the extent required by the research or statistical purpose.

(4) The controller may publish personal data only if the data subject has provided consent or if doing so is indispensable for the presentation of research findings on contemporary events.

Greece

As per your questions, kindly note, that although the draft law, regarding the implementation of GDPR, was entered in public consultation back in February 2018, up to date the final greek Law implementing/supplementing GDPR has not yet been published.

Ireland

Are there national exceptions in your member state for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

Yes. Section 42 of the Irish Data Protection Act 2018 (the “Act”) allows for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

In order for such processing to be lawful it must be done subject to suitable and specific measures to safeguard the fundamental rights and freedoms of data subjects, in accordance with Article 89 of the GDPR.

Section 42 requires that such processing shall respect the principle of data minimisation and that where the identification of the data subject is not required for the purposes of the processing it shall be carried out without identification being used.

Section 54 of the Act allows for processing of special categories of personal data, in accordance with the principles outlined in Section 42, is lawful where such processing is necessary and proportionate for:

- (a) archiving purposes in the public interest,
- (b) scientific or historical research purposes, or
- (c) statistical purposes.

Ireland has introduced special measures for data controllers conducting “Health Research” which would be relevant if the scientific research in question met the definition of Health Research (the “Health Research Regulations”).

The broad scope of activities constituting health research is maintained in the Health Research Regulations where the term “Health Research” is defined as any of the following scientific research for the purpose of human health:

1. Research with the goal of understanding the normal and abnormal functioning of the human body;
2. Research specifically concerned with developing innovative strategies, products or services to diagnose, treat or prevent disease or injury;
3. Research with the goal of improving the diagnosis, treatment, rehabilitation and palliation of human disease and injury and of improving the health and quality of life of individuals;
4. Research with the goal of improving the efficiency and effectiveness of health professionals and the health care system; and
5. Research with the goal of improving the health of the population as a whole or any part of the population through better understanding of social, cultural, environmental, occupational and economic factors on determining health status.

The Health Research Regulations lists a number of “suitable and specific measures” that controllers of personal data engaging in Health Research must comply with. Importantly, this includes a requirement to obtain the explicit consent of the data subject prior to the commencement of the Health Research. A derogation to this consent requirement is possible but only with the consent of a committee appointed by the Irish Minister for Health.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

Yes. Section 61 of the Act provides for a restriction on the exercise of data subjects’ rights in relation to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

Section 61 restricts the rights of data subjects set out in in Articles 15, 16, 18 and 21 of the GDPR in relation to processing for scientific or historical research purposes or statistical purposes to the extent that:

- (a) the exercise of any of those rights would be likely to render impossible, or seriously impair, the achievement of those purposes, and

(b) such restriction is necessary for the fulfilment of those purposes.

Section 61 provides that where the processing under that section serves another purpose at the same time, only the processing in relation to archiving purposes in the public interest, scientific or historical research purposes or statistical purposes will be covered by the this derogation of data subject rights.

Italy

Are there national exceptions in your member state for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

First of all, it should be noted that the legislative decree no. 196/2003 (as amended by the legislative decree no. 101/2018 containing provisions in order to adapt the national legislation to GDPR, hereinafter “**Italian Data Protection Code**” or “**IDPC**”) expressly regulates the processing of personal data for scientific research purposes pursuant to Article 89 GDPR.

In particular, it is worth mentioning the following provisions:

- **Art. 99 IDPC (“Duration of the processing”)** provides for that the processing of personal data in the context of scientific research can be carried out even after the period of time necessary to achieve the different purposes for which the data were originally collected or processed. In addition, personal data, whose processing is ended, can be stored or transferred to another data controller, for scientific research purposes.
- **Art. 105 IDPC (“Method of processing”)** clarifies that (i) personal data processed for scientific research purposes cannot be used to make decisions concerning the data subject or for purposes other than scientific research; (ii) the scientific research purposes must be clearly identified and disclosed to the data subject; (iii) whenever, according to the ethical rules adopted by the Italian Data Protection Authority (hereinafter, “**IDPA**”), a subject is allowed to respond in the name and on behalf of another person (e.g. a family member or cohabitant), the data subject can be provided with the needed information also through the respondent; (iv) with regard to the processing, for scientific research purposes, of data originally collected for other purposes, it is not needed to provide the data subject with information on the data processing when it requires efforts not proportional to the protected rights, as long as adequate forms of publicity are adopted pursuant to the ethical rules issued by the IDPA.
- **Art. 110 IDPC (“Medical, biomedical and epidemiological research”)** specifies that the data subject’s consent is not required for the processing of health data for the purpose of scientific research in the medical, biomedical or epidemiological fields (i) when scientific research is carried according to Italian or EU provisions pursuant to Art. 9 (2j) GDPR, provided that the data controller conducts and makes public a data protection impact assessment in accordance with Articles 35 and 36 of the GDPR, assessing the necessity and proportionality of the processing, the risks to the rights and freedoms of data subjects and the security measures envisaged to address those risks; or (ii) when, for particular reasons, providing the data subjects with the needed information is impossible or involves a disproportionate effort, or if it can make impossible or seriously jeopardize the achievement of the research purposes, provided that (a) the data controller adopts appropriate measures to protect the rights, freedoms and legitimate interests of data subjects, (b) the research programme is subject to a favorable reasoned opinion by the competent Ethics Committee and (c) is subject to a prior consultation with the IDPA, following the outcome of an impact assessment, pursuant to Articles 35 and 36 GDPR.
- **Art. 110 bis IDPC (“Additional processing by third parties of personal data for the purpose of scientific research or for statistical purposes”)**, the re-use of personal data – including particular categories of data - for scientific research purposes is allowed, when: (i) it is carried out by third parties which mainly carry out scientific research activities; (ii) providing the data subject with the needed information is impossible or involves a disproportionate effort, or it is likely to make impossible or seriously jeopardize the research; (iii) it is subject to the prior authorization of the IDPA, subject to the adoption of appropriate measures in accordance with art. 89 of the GDPR.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

According to Art. 106 of IDPC, the IDPA has to issue the ethical rules (i.e. codes of conduct) for public and private organizations, including scientific companies and professional associations, interested in the processing of data for statistical or scientific research purposes, aimed at identifying adequate guarantees for the rights and freedoms of the data subject, pursuant to Article 89 GDPR.

In this respect, paragraph 2 of Art. 106 specifies that the above mentioned codes of conduct identifies the cases in which the rights referred to in Art. **15, 16, 18, and 21 GDPR** may be limited pursuant to Art. 89 (2) GDPR.

On December 19th, 2018, the IDPA published the “**Code of Conduct concerning the data processing for statistical or scientific research purposes**” (hereinafter the “**Code**”) which applies to all the processing activities carried out for statistical and scientific purposes carried out by universities, other research bodies and institutes and scientific societies, as well as researchers working within these universities, bodies, research institutes and members of these scientific societies.

The Code does not apply to the processing of personal data for statistical and scientific purposes connected with health care activities carried out by health professionals or health organizations.

Article 12 of the Code regulates the exercise of the data subject's rights, providing for that - in case of exercise of the rights under Articles 15 et seq. GDPR - if changes to the data concerning the data subject are needed, the data controller shall take note of the requested changes, without amending the data originally entered in the database.

In addition, it is worth mentioning that Art. 110 (2) IDPC provides for that - in case of exercise of the right to rectification (Art. 16 GDPR) regarding the processing of health data for the purpose of scientific research in the medical, biomedical or epidemiological fields - the rectification and integration of data are noted without amending the data, when the outcome of these operations does not affect substantially the results of the research.

Lithuania

Are there national exceptions in your member state for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

Law on Ethics of Biomedical Research provides that before involving a person in biomedical research (with the exception of research on the human biological samples and/or health information processed in a biobank), a person's consent to participate in research must be obtained. A person's consent to participate in research in respect of a minor's participation in biomedical research shall be given by the minor's legal representatives, however if the minor who is capable of understanding the information provided to him expresses his wish not to participate in the biomedical research, the minor's participation in the research shall not commence, unless this is contrary to the interests of the minor.

Are there national derogations from the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

We are not aware of any local derogations in the context of Article 89 (2) of the GPDR.

Malta

Article 6 of the Data Protection Act (Chapter 586, Laws of Malta) does provide for derogations in relation to the processing of personal data for scientific purposes to (1) the Access Right, (2) Rectification Right, (3) Restriction (4) Right to Object ... as per the following extract:

- (1) Subject to the provisions of sub-article (4), controllers and processors may derogate from the provisions of Articles 15, 16, 18 and 21 of the Regulation (GDPR) for the processing of personal data for scientific or historical research purposes or official statistics in so far as the exercise of the rights set out in those Articles:
 - a. is likely to render impossible or seriously impair the achievement of those purposes; and
 - b. the data controller reasonably believes that such derogations are necessary for the fulfilment of those purposes.
- (2) [...]
- (3) Where data processing referred to in sub-articles (1) [..] serves at the same time another purpose, the derogations shall apply only to processing for the purposes referred to in those sub-articles.
- (4) Processing for the purposes referred to in sub-articles (1) a[...] shall be subject to appropriate safeguards for the rights and freedoms of the data subject, including pseudonymisation and other technical and organisational measures to ensure respect for the principle of data minimisation: Provided that, where such purposes can be fulfilled by processing which does not permit, or no longer permits, the identification of data subjects, those purposes shall be fulfilled in that manner.

Netherlands

Are there national exceptions in your member state for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

General exceptions

In accordance with article 9(2)(j) of the GDPR, article 24 of the Dutch GDPR Implementation Act ("Implementation Act") provides for a specific exception to the prohibition on processing special categories of personal data for scientific or historical research or statistical purposes. This provision corresponds with previous Dutch data protection law (the Dutch Data Protection Act, which applied in the Netherlands prior to the GDPR).

Under Dutch data protection law, there are two possibilities to lawfully process special categories of personal data for scientific research or statistical purposes: 1) with explicit consent on the basis of article 9(2)(a) of the GDPR and article 22(2)(a) of the Implementation Act, or 2) on the basis of the specific exemption provided for in article 24 of the Implementation Act.

The first option (explicit consent) is preferred. The second option (the exemption provided for in article 24 of the Implementation Act) states that the prohibition on processing special categories of personal data does not apply if the following cumulative conditions are met:

- a. processing is necessary for scientific or historical research purposes or statistical purposes in accordance with Article 89(1) of the GDPR;
- b. the research referred to in a. serves a public interest;
- c. it is impossible or would involve a disproportionate effort to request explicit consent; and
- d. safeguards have been put in place for the processing such that the data subject's private life is not disproportionately compromised.

The specifics of the safeguards referred to in (d) will depend on the case at hand. Such safeguards could for example relate to the access to data, confidentiality and the disclosure of the results of the research.

Exception specific to the processing of personal data relating to criminal law matters

Contrary to previous Dutch data protection law, personal data relating to criminal law matters ("criminal data") are not considered a special category of personal data under the GDPR and the Implementation Act. As a consequence of this, the exceptions to the prohibition on processing special categories of personal data contained in the GDPR and the Implementation Act do not apply to criminal data. However, article 32 of the Implementation Act stipulates that a number of exceptions to the processing prohibition for special categories of personal data also apply to the processing of criminal data. Strictly speaking, there is no need for an exception. After all, the processing prohibition does not apply to criminal data. Rather, article 32 of the Implementation Act should be regarded as a specification of the conditions under which processing criminal data is permitted.

Article 32(f) of the Implementation Act provides that criminal data may be processed if necessary for scientific or historical research purposes or statistical purposes in accordance with article 89(1) of the GDPR and the conditions referred to in article 24(b) to (d) of the Implementation Act have been met. For these conditions, please refer to conditions (b) to (d) mentioned above.

Exception specific to the processing of genetic data

In accordance with article 9(4) of the GDPR, article 28 of the Implementation Act provides for further conditions with regard to the processing of genetic data. On the basis of article 28(2)(b) of the Implementation Act, the prohibition on processing genetic data does not apply if:

- The processing is necessary for scientific research that serves a public interest or for statistical purposes if:
- the data subject has given his or her explicit consent; and
 - safeguards have been put in place for the processing such that the data subject's private life is not disproportionately compromised.

With regard to this last requirement, the Subdistrict Court of Amsterdam ruled that the private life of an employee was disproportionately compromised in a case where an employer used DNA testing to find out which of its employees had written a letter which was regarded by another employee to be threatening and intimidating. The Subdistrict Court of Amsterdam did not take the results of this DNA test into account in its decision, for that it was obtained unlawfully by the employer (Subdistrict Court of Amsterdam, 19 October 2005, JAR 2006/1).

Consent as referred to in article 28(2)(b) of the Implementation Act is not required if it proves impossible or would involve a disproportionate effort to request explicit consent on the basis of article 28(3) of the Implementation Act.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

Article 89(2) of the GDPR allows Member States to provide by national law for derogations from the rights of data subjects referred to in articles 15, 16, 18 and 21 of the GDPR when their personal data are processed for scientific or historical research or statistical purposes.

In the Netherlands, article 44 of the Implementation Act provides institutions or services the possibility to exclude the application of the rights of data subjects referred to in articles 15, 16 and 18 of the GDPR when they carried out the processing for scientific research or statistical purposes and the necessary steps have been taken to ensure that the personal data can be used solely for those purposes. It is up to the data controller to consider in practice whether and to what extent this possibility will be used. There is *no obligation* for the controller to exclude the application of these rights.

The Implementation Act does not provide a possibility to exclude the application of the right to object (article 21 of the GDPR), although the GDPR leaves room for this. The application of the right to object was not excluded for scientific research purposes under previous Dutch data protection law either and the Dutch legislator did not decide to take a different approach in the Implementation Act (Parliamentary Papers II 2017/18, 34851, 3, p. 126).

Poland

Are there national exceptions in your member state for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

1. Polish law provides several exceptions for processing special categories of data in the context of scientific research. The most important exceptions can be found in the following acts:

- a. Act of 28 April 2011 on the Information system in health care;
- b. Act of 18 December 1998 on the Institute of National Remembrance;
- c. Regulation of the Minister of Justice of 1 July 2015 on the detailed rules and manners of processing and transfer of personal data collected in the National Criminal Register for statistical purposes and scientific research;
- d. Regulation of the Minister of Justice of 13 March 2017 on the processing and transfer of personal data collected in the Register of Sexual Offenders for statistical and scientific research purposes.

Ad a. The Act on the Information system in health care provides that the data contained in the medical records could be made available for statistical and scientific or scholar research purposes only in a form that makes it impossible to relate to a particular natural person;

Ad b. The Act on the Institute of National Remembrance stipulates that the data collected by this Institute (including sensitive data) could be disclosed for the purposes of scientific research. Additional formal conditions need to be fulfilled to access such a data;

Ad c. Regulations of the Minister of Justice regarding the National Criminal Register provides that personal data collected in the National Criminal Register (criminal records) shall be made available for scientific purposes only upon written consent of the Minister of Justice. In justified cases, data might be deprived of information identifying the person. Additional formal conditions need to be fulfilled to access such a data;

Ad. d Regulation of the Minister of Justice on the processing and transfer of personal data collected in the Register of Sexual Offenders provides that the data collected in the Register (criminal records on sexual offences) are made available for scientific purposes. Additional formal conditions must be fulfilled to access such a data.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

- a. At the moment, there are no national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR).
- b. However, the draft Law implementing GDPR which is undergoing a legislative process provides such derogation. This derogation is to be inserted in the Law of 20 July 2018 on Higher Education and Science. The date of entry into force of the Law implementing GDPR is not yet know. If this derogation enters into force, it will provide that with respect to the processing of personal data by higher education institutions and scientific/research institutes, for the purposes of scientific research, Article 15, Article 16, Article 18 and Article 21 of the GDPR shall not apply if it is possible that the rights set out in those provisions will prevent or seriously impede the implementation of the objectives of research and if those exemptions are necessary to achieve these objectives (draft new article 496 b section 1 of the Law of 20 July 2018 on Higher Education and Science).

Portugal

The Portuguese Law that will implement and approve the derogations to the GDPR has not been approved. The initial draft law was very criticised and it is still under discussion in the Parliament. Up to April 2019 the final version of the draft Law that will be voted in the Parliament has not yet been published.

Romania

Are there national exceptions in your Member State for the processing of special categories of personal data in the context of scientific research (Article 9(2)(j) of the GDPR)?

No. The GDPR implementation law does not provide any additional exemptions other than those set out in the question 2 below. However, the Romanian legislation, provides that the processing of genetic data, biometric data, as well as of data concerning health with the aim of establishing an automated decision-making process for profiling is allowed, where (a) the explicit consent of the data subject has been obtained; or (b) if the processing is carried out under explicit Romanian/EU law in accordance with Article 9(2)(g) GDPR (reasons of substantial public interest) and in each case with the provision of appropriate safeguards.

Are there national derogations to the rights of data subjects in the context of scientific research (Article 89(2) of the GDPR)?

Yes. According to the Article 8 of the GDPR implementation law data subject's rights set out in Articles 15, 16, 18 and 21 GDPR do not apply to personal data which are processed for scientific or historical research to the extent that the rights referred to in GDPR Articles 15, 16, 18, 21 are such as to render it impossible or seriously detrimental to the achievement of the specific purposes and such derogations are necessary for the achievement of those purposes. However, such derogations are applicable only subject to the existence of appropriate safeguards for the rights and freedoms of the data subjects as provided by Art. 89 para. (1) GDPR.

Slovenia

Slovenia is one of the EU member states that has not adopted a GDPR implementing law yet. We will regulate this matter in our national legislation with the new Personal Data Protection Act (“ZVOP-2”). **The proposal of ZVOP-2 is currently in the legislative process.** It will regulate certain content such as the use of health, biometric and genetic data, some procedural aspects (e.g. sanctions and legal remedies) and the relation to other areas and rights (e.g. access to public information, **use of personal data for scientific and statistical purposes**).

The **currently valid ZVOP-1** regulates **scientific research** in Articles 17, 19, 22 and 23:

- Article 17 addresses processing for historical, statistical and scientific research purposes and allows further processing of personal data for such purposes, irrespective of the initial purpose (of collection).
- Pursuant to Article 19 (informing the individual of the processing of personal data), if personal data were not collected directly from the individual to whom it relates, the data controller or his representative must communicate to the individual the following information no later than on the date of recording or supply of personal data to the data recipient: data on the data controller and his possible representative (personal name, title or official name respectively and address or seat respectively) and the purpose of the processing of personal data. If in view of the special circumstances of collecting personal data from the previous paragraph there is a need to ensure lawful and fair processing of personal data of the individual, the person from the previous paragraph must also communicate to the individual additional information, and in particular: information on the type of personal data collected, a declaration as to the data recipient or the type of data recipients of his personal data and information on the right to consult, transcribe, copy, supplement, correct, block and erase personal data that relate to him. However, the mentioned information shall not need to be ensured if in order to process personal data for historical, statistical or scientific-research purposes it would be impossible, would incur large costs or disproportionate effort, or would require a large amount of time, or if the recording or supply of personal data is expressly provided by statute.
- According to Article 22 (supply of personal data), data controllers shall be obliged against payment of the cost of supply, unless otherwise provided by statute, to supply personal data to data recipients. Irrespective of this, data controllers in the public sector shall be bound to supply to data recipient in the public sector personal data without payment of the cost of supply, unless otherwise provided by statute or unless it involves use for historical, statistical or scientific-research purposes.
- Article 23 addresses the protection of personal data of deceased individuals, saying that data controller may supply data on a deceased individual only to those data recipients authorised to process personal data by statute. Irrespective of the previous paragraph, data controller shall supply data on a deceased individual to the person who under the statute governing inheritance is the deceased person’s legal heir of the first or second order, if they demonstrate a lawful interest in the use of personal data and the deceased individual did not prohibit in writing the supply of such personal data. Unless otherwise provided by statute, a data controller may also supply data from the previous paragraph to any other person intending to use such data for historical, statistical or scientific-research purposes if the deceased individual did not prohibit in writing the supply of such personal data.

The (draft) proposal of ZVOP-2:

- The regulation in relation to deceased individuals remains the same as in ZVOP-1 (Art. 23) but is now in Article 10.
- Article 12 of ZVOP-2 is the same as Article 9(2)(j) of the GDPR, regarding scientific research (Art. 12(2)(j) ZVOP-2).

ZVOP-2 laid down **special rules on the processing of personal data for scientific research**, historical, scientific and archive purposes in Chapter VII. Especially in Article 79 (Processing of personal data for scientific research, historical research and statistical purposes):

- According to the first paragraph of Article 79, the data controller may further process personal data for scientific research, historical research and statistical purposes, irrespective of the original purpose of the

collection (as in ZVOP-1 in Article 17), and another recipient of personal data for the same purposes. Thus, processing for other purposes is carried out in respect to the provisions of point (b) of the first paragraph of Article 5 and Article 89 of the GDPR. Processing for these other purposes, which are in the public interest, is permissible on the following legal basis: if the individual, to whom personal data relate, has given prior written consent for such processing (i.e. a specific type of consent determined systematically in ZVOP-2); if it is obtained and further processed in an anonymous form (meaning it is no longer personal data); or if so provided by a sectoral law (that is, a specific legal basis).

- The second paragraph sets out a strict system of who can act for the purposes of the first paragraph, namely a registered scientific research organization or registered researchers in accordance with the act governing research and development. It is then stipulated that, for the processing referred to in the first paragraph, they may inspect or acquire special types of personal data from the personal data controller, or other personal data in a pseudonymized form if they submit a study report showing: the actual existence of a research; that the effective implementation of the research or its purpose cannot be achieved without the processing of certain personal data or this would be linked to disproportionate effort or costs (the organisation or researcher must demonstrate the necessity and appropriateness of the processing of personal data), that personal data that are indispensable for the effective conduct of the research cannot be obtained with the consent of the individual (which the organization or researcher must demonstrate). This shows that strict cumulative conditions are proposed for obtaining personal information without consent, a special (sectoral) law, without anonymization.
- According to the third paragraph, the data recipient (organization or researcher) referred to in the second paragraph shall be transmitted the data in a pseudonymized form, and in the fourth paragraph the methods of consultation are regulated.
- The fifth paragraph sets out strict conditions for the content of the study and the necessity of the (annexed) implementation of the impact assessment in relation to the protection of personal data under Article 37 of ZVOP-2.
- Pursuant to the sixth and seventh paragraph, the study is accompanied with an impact assessment and personal data are usually destroyed after the research, but exceptions are possible; namely personal data acquired by the recipient in accordance with the first paragraph and the second paragraph of this Article shall be destroyed or irreversibly anonymised at the end of the research unless otherwise provided by the law, if the individual has not consented to the further retention of personal data or if this is not relevant for the purpose of the research to be carried out. However, the recipient of personal data must inform the data controller, who provided him with personal information in writing, immediately after their destruction, of when and in what manner he destroyed them.
- Paragraph 8 is one of the most important paragraphs of the article, since it determines the publication of the results of research: in an anonymous form (the principle of proportionality applied), unless ZVOP-2 or another law specifies otherwise, or if the individual provided written consent for publication in a non-anonymous form or if for such publication at the time after the death of the individual, the written consent of certain persons in the exclusive order (spouse, partner, same-sex partner, children or parents of a deceased individual) is given. However, the data controller may not publish un-anonymised personal data if this is contrary to the interest of secrecy or the confidentiality of decision-making procedures, or these procedures have not yet been completed.
- **Paragraph 9 sets out the safeguards and derogations relating to processing with regard to the purposes of scientific research:** The data subject may invoke the right to rectification (**Article 16 of the GDPR**) only if the data controller has obtained the information from him directly and only up to the start of the processing for statistical purposes. When personal data is processed for statistical purposes, the data subject does not have the right of access (**Article 15 of the GDPR**) nor the right to restriction of processing (**Article 18 GDPR**), but only if the providing of information or copies of an individual's personal data would require a disproportionate effort, or when the data controller proves that he cannot identify the data subject in accordance with Article 11 of the General Regulation.

- Paragraph 10 stipulates that the provisions of Article 79 of the ZVOP-2 do not interfere with the (sectoral) provisions of the Protection of Documents and Archives and Archival Institutions Act.

And in Article 80 (Address processing for contacting individuals for scientific research, historical research and statistical purposes):

- According to the first paragraph, regarding the processing of personal data for purposes of scientific research, historical research or statistical surveys, the data controller is exceptionally allowed to process personal data of the target group of individuals for the purpose of obtaining consent to process their personal data or for obtaining additional information or explanations (for the purposes stated above).
- According to the second paragraph, the data controller may, on the basis of collections with which he legally disposes, contact the individuals against payment in order to obtain consent for another recipient (and for the fulfilment of the purposes referred to in the previous paragraph): who does not have the basis for processing personal data in the law or consent; and who, with the study referred to in the fourth paragraph of the preceding article, shows that personal data will be processed on a scientific-research basis after receiving the consent. These are cases where the recipient wants to obtain consent but does not have personal data; therefore, contacting the data subject is carried out for him by a public sector recipient, against the payment of costs, and only for the purposes of the first and second paragraphs.
- Pursuant to the third paragraph, only the personal name, address of permanent or temporary residence, contact telephone number or contact email address (the principle of proportionality and the specific purpose of the processing) can be processed for the purpose of contacting in the first and second paragraphs.
- According to the fourth paragraph, the transmitted or processed personal data may be processed exclusively for the purpose of the research and should be deleted as soon as they are no longer needed (dedicated processing of personal data and the definition of erasure referred to in point 6 of the third paragraph of Article 6 of ZVOP-2).
- Paragraph 5 stipulates that the provisions of Article 80 of the ZVOP-2 do not interfere with the (sectoral) provisions of the Protection of Documents and Archives and Archival Institutions Act, since for the field of archives, the (subordinate) options apply, for example, scientific research and historical research.

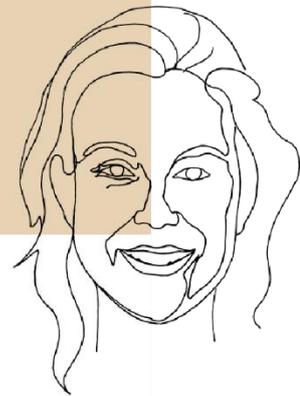
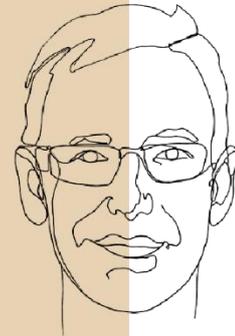
Regardless of the above, please bearing in mind that the proposal of ZVOP-2 is currently in the legislative process therefore, some provisions may still be amended until the adoption of the Law.

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