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## What is important for Data Protection in science in the future?

General and specific changes in data protection  
for scientific use resulting from the EU General  
Data Protection Regulation

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# What is important for Data Protection in science in the future?

## General and specific changes in data protection for scientific use resulting from the EU General Data Protection Regulation<sup>1</sup>

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On 14th April the General Data Protection Regulation (GDPR) was passed by the EU Parliament.<sup>2,3</sup> It came into force in May 2016 and will – after possible modification of national legislation – become directly applicable law in the EU member states. The GDPR replaces the European Data Protection Directive (DPD) from 1995<sup>4</sup> as well as the individual national data protection laws within the EU member states.

The GDPR comprises in total 99 articles which are explained in 173 Recitals. One goal of the new regulation is to provide an appropriate data protection framework for the current challenges resulting from new technological developments, such as cloud computing and big data. Furthermore, the aim is to harmonize data protection regulation in EU member states. With the GDPR a unified regulatory structure for the whole of the European Union has been created, only certain well-defined aspects of which can be expanded or refined by the member states.

In contrast, the Data Protection Directive from 1995 gave the member states much more leeway. With the new regulations there will be a single unified European data protection law, which differs in some parts significantly from the old directive. Moreover, in the area of

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<sup>1</sup>This paper was originally published in German as RatSWD Working Paper 257/2016.

<sup>2</sup>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), 2016.

<sup>3</sup>See also the condensed version of this paper in the Zeitschrift für Datenschutz (Schaar, K., 2016).

<sup>4</sup>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, 1995.

research, certain questions need to be reevaluated with regard to data protection and research practice needs to be modified accordingly.

That the personal data of participants of scientific studies need to be protected is completely uncontested, and this is also the case within the scientific community. In this spirit, the German Data Forum (Rat für Sozial- und Wirtschaftsdaten, RatSWD), an institution which aims to improve the scientific data infrastructure for empirical research, stated during the negotiations regarding the GDPR that data protection is essential for empirical research. Participants of scientific studies need to be sure that their anonymity will be guaranteed, because otherwise it could lead to a loss of trust and less acceptance for scientific research (RatSWD, 2015, p. 2).

This loss of trust could have a negative influence on people's willingness to provide surveys with, for example, sensitive data, such as political or religious orientation, or to take part in medical studies if they cannot be sure that this information is kept completely confidential. In the area of survey research, the new regulations can also be of help, since "the reliable regulation of ethical and data protection issues has significant relevance to research practice, especially with respect to a generally falling willingness to participate in such studies" (Kämper, 2016, p. 6).

Potential study participants could be even more skeptical if they are also asked to provide genetic data or geo-data which could be traced back to an individual even without disclosing common identification items (name, address, date of birth). Kämper (2016) points out uncertainties which require a rethinking of research ethics and data protection. Various phenomena contribute to the need for new regulation: requirements by scientific journals regarding documentation of data used for analysis; technological developments in the area of big data and data linkage increasing the possibility of de-anonymization; more interdisciplinary research and the increase of secondary data usage, which could be in conflict with the informed consent originally given for the primary data usage (Kämper, 2016, p. 4).

The framework for data protection and the protection of participants are therefore important for scientific research. This is true for the traditional qualitative and quantitative empirical research which processes personal data, be it from social science, psychology or medicine, and applies all the more to the new research area of "personalised" medicine, to open access and big data, as well as to the increasingly widespread multi- and interdisciplinary research projects, in which medical, socioeconomic and genetic data are collected and analysed.

## **General changes with relevance for research**

A large number of changes result from the GDPR (Wytibul, 2016b) which have a direct influence on research using personal data. Although the processing of personal data for research or for statistical purposes is in some ways privileged (Die Bundesbeauftragte für den Datenschutz und die Informationsfreiheit, 2016, p. 31), scientific research still needs take adequate measures to guarantee the civil liberties of the study participants.

## **Higher penalties for privacy breaches**

In general the GDPR increases sanctions for breaches against the regulation. The current data protection law of Germany (Bundesdatenschutzgesetz, BDSG) in §43 allows fines up to €300,000<sup>5</sup>, whereas the new regulation allows fines of up to €10 million or €20 million for the controllers and up to two or four percent of the total worldwide annual turnover of the preceding financial year for companies (GDPR, art. 83, para. 4,5).

## **Responsibility**

The so-called ‘controller’ needs to ensure that the processing of data follows the rules of the regulation and also need to be able to demonstrate this compliance (GDPR, art. 5, para. 2). The ‘controller’ is “the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data” (GDPR, art. 4, para. 7). This can be, for example, the research institution as represented by its director.

The controller can and, in certain cases, must designate a data protection officer (GDPR, art. 37).<sup>6</sup> Unlike the German Data Protection Law, the data protection officer does not only have to work towards the compliance of the regulation (BDSG, art. 4g para. 1). Under the new regulation, data protection officers need to monitor the compliance with the regulation, train the staff and raise their awareness, advise the controllers regarding their policies and also oversee these policies. The data protection officer is also responsible for providing advice on the data protection impact assessment and monitoring its performance (GDPR, art. 39, para. 1). This could lead to the data protection officers monitoring the applied practices of data use

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<sup>5</sup> Note that the fines have varied among the member states up to now.

<sup>6</sup> The GDPR provides an opening clause for the national specification of the regulation (GDPR, art. 37, para. 4). Whereas the GDPR does not require a data protection officer dependent on the number of persons involved in data processing, in Germany a data protection officer needs to be designated as soon as more than 20 staff members collect, process or use personal data (§4 f. BDGS). Because of the opening clause mentioned, this regulation could be kept in Germany.

more carefully, because they have a higher risk of liability than before (Wytibul, 2016a, p. 205).

The new regulation is significant in the field of science because the officially designated data protection officer needs to be much more closely involved during the conception of research projects in order to be able to fulfill his duties. This raises the question of how this close involvement in the ethical approval process via ethics committees could be achieved in a reasonable way. Such ethics committees are well established in Germany for the medical sciences and psychology and their introduction is currently being discussed with regard to the social sciences (Kämper, 2016; Silverberg, 2016; Unger & Simon, 2016).<sup>7</sup>

### **More transparency**

The GDPR requires more transparency in many areas (GDPR, art. 12–15). All information must be provided “in a concise, transparent, intelligible and easily accessible form, using clear and plain language” (GDPR, art. 12, para. 1). This applies, for example, to the information regarding the purposes of the data collection, the processing of the data, as well as any planned transfer of the personal data to third parties. Additionally, the participants need to be informed about their rights (GDPR, art. 13).

For instance, information must be given to the participants about their right of access, including their “right to be forgotten” (GDPR, art. 17), and also about their right of rectification or erasure of their data (art. 13, para. 2b). Also the general right of access by the data subject has been strengthened (art. 15) and all information needs to be given in an easily understandable form. This leads to rigorous requirements for documentation, because without documentation the institutions, processing the data, cannot provide information about the transfer of data or the types of personal data that were collected, copies of which may even need to be handed out to the data subject. Although the information necessary to allow “informed consent” for participation in a research study is already supposed to be adapted to the target group, it will be a real challenge to provide understandable information about the existing research data as long as they are still connectable and not anonymised, unless specific regulations for science are established on a national level.

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<sup>7</sup> In the UK and the US, ethics committees are already established also for the social sciences. In Germany there are tendencies to establish them, but they are not yet widespread (see also Oellers and Wegner, 2009).

### **Data Protection Impact Assessment aims to minimise risks**

The GDPR distinguishes various risks which the data users can be exposed to and in certain cases requires a “data protection impact assessment” (GDPR, art. 35). In particular, this needs to be carried out if new technologies are applied or certain categories of data (sensitive data) are processed. These include “personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation” (GDPR, art. 9, para. 1).

These core data, however, are frequently collected and processed in social scientific and medical studies. With respect to the new law, a data protection impact assessment needs to be carried out by the controller in cooperation with the data protection officer (GDPR, art. 35, para. 2). In the impact assessment, the purposes and the method of the processing of the data need to be described, the “necessity and proportionality of the processing operations in relation to the purposes” need to be assessed, the “risks to the rights and freedoms of the data subjects” need to be evaluated, and “measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data” need to be described (GDPR, art. 35, para. 7).

### **Research-specific changes**

#### **Informed Consent but with expanded purpose limitation**

Under the new law, participants still need to be informed about the purposes and modalities of the data collection and processing (GDPR, art.12). The consent must be given freely and can be withdrawn at any time (GDPR, art. 7). The consent can be made “by a written statement, including by electronic means, or an oral statement”, which needs to be documented (GDPR, recital 32). A lack of response or inactivity do not constitute consent (ibid.). Thus, a central requirement of the GDPR is active consent for the data usage on a freely given basis and after detailed information about the purposes of the data collection.

A substantial change in the GDPR is the definition of “purpose limitation”. The 1995 data protection directive states that the processing of personal data “must be adequate, relevant and not excessive in relation to the purposes for which they are processed; whereas such purposes must be explicit and legitimate and must be determined at the time of collection of the data” (DPD, recital 28). The new regulation, however, stipulates that data can be “collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public

interest, scientific or historical research purposes or statistical purposes shall (...) not be considered to be incompatible with the initial purposes ('purpose limitation').“ (GDPR, art. 5, para. 1b)<sup>8</sup>

Furthermore, the recitals of GDPR mention the possibility of consenting to data usage for certain areas of scientific research: “It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose “(GDPR, recital 33)

In a first statement, the RatSWD interpreted this as a positive change for science (RatSWD, 2015). The consent form for participants of scientific studies could therefore define certain areas which are larger than the research question originally described. This would also be an opportunity for qualitative research, in which the research question is developed during fieldwork in the context of the theoretical sampling (Glaser, 1992; Strauss & Corbin, 1990), to ensure compliance with data protection regulation through appropriate phrases in the consent forms. Thus, participants could be informed about the general research question and the procedure by which new research questions could emerge during the research process.<sup>9</sup>

Consent forms should contain opt-in/opt-out possibilities, so that participants can decide how extensively their data can be used and, in a research context, how they can be transferred to other scientists or linked with other information. If subsequently the data are to be used in a different context to the original one, participants still need to be informed (GDPR, art. 14, para. 4). Overall, the regulation of purpose limitation is not very precise, because the point at which further processing of data becomes contrary to the original purpose is not well defined (see Roßnagel & Nebel, 2016, p. 6).

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<sup>8</sup> The difference to the German law is even larger than that to the DPD: The German Data Protection Law allows the usage and further processing only if the data subject has given his or her explicit consent (BDSG para.14 (2)(2). The BDSG also provides exceptions for scientific research (para. 14 (2)(9)).

<sup>9</sup> The problem of obtaining informed consent for qualitative research projects is mentioned by Kämper (2016, p. 7) and Unger and Simon (2016, pp. 10 f.). The argument of Unger and Simon (ibid., p. 11), that one could not ask all fans of a football game for their consent in the context of participating observation, is– in my opinion – not convincing. One could record such observations in field notes in an anonymous way, which would then be data to which the GDPR would not be applicable. As soon as the observation is personalised or individuals are interviewed, the participants need to be informed and need to consent actively (see GDPR, recital 32 and art. 13). See also the instructive working paper of the RatSWD working group “Data protection and qualitative research”, which deals in particular with the data protection compliance of consent forms for the processing and further use of qualitative interviews. It also provides examples for consent forms for qualitative interviews (Liebig et al., 2014).



In all cases of further processing of data for research purposes “in accordance with the regulation the rights and freedoms of the data subject” should be ensured (GDPR, art. 89, para. 1). In particular, this means that technical and organisational measures must be applied which guarantee that the data subject is not identifiable.

### **Anonymisation and pseudonymisation for long-term scientific data processing**

The question as to whether scientific data need to be completely anonymized, which was discussed during the development of the GDPR, has also been resolved. Contrary to the stipulation in the draft of the GDPR, complete anonymization of data is no longer explicitly required. Such a requirement would have been problematic for, say, longitudinal research projects, because it would not have been possible to merge the new data with pre-existing data from the same participants (RatSWD, 2015).

In fact, the pseudonymisation of participants’ data, alongside anonymization, is a possible way of processing the data, as long as further processing “does not permit or no longer permits the identification of data subjects” (GDPR, art. 89, para. 1). However, it must be considered whether it really is no longer possible to identify a person. To achieve this “account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments.” (GDPR, recital 26)

This corresponds with the maxim of German data protection law which does not require complete but only effective removal of personal references. Paragraph 3(6) of the BDSG defines ‘anonymisation’ as “the modification of personal data in such a manner that particulars about an individual cannot be matched to a specific or identifiable person, or only with a disproportionate investment of time, cost and labour.” (BDSG, para. 3 (6))<sup>10</sup>

Correspondingly, when pseudonymisation and anonymisation procedures are chosen – for instance within the data protection impact assessment mentioned – the concrete risks of de-anonymisation, including economic and technical factors, need to be taken into account. In this regard, the rapid technological development needs to be considered, because a procedure which guarantees a sufficient standard of anonymization at the moment might not guarantee that same protection a few years hence. Thus, anonymisation procedures need to involve a

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<sup>10</sup> Translation by the author. Original text: „Anonymisieren das Verändern personenbezogener Daten derart, dass die Einzelangaben über persönliche oder sachliche Verhältnisse nicht mehr oder nur mit einem unverhältnismäßig großen Aufwand an Zeit, Kosten und Arbeitskraft einer bestimmten oder bestimmaren natürlichen Person zugeordnet werden können.“

form of “protection buffer” against potential risks in the future. The GDPR explicitly indicates: “The principles of data protection should (...) not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.” (GDPR, recital 26) This means that in as far as it is not possible to link the research data to the participants, the regulation no longer applies.

As long as the persons are no longer identifiable, data can be processed in a scientific context (GDPR, art. 89, para. 1). In this state, the data are not personal data anymore, because they cannot be connected to a natural person (GDPR, art. 4, para. 1) and therefore they are not subject to the protection of the regulation anymore. A new and interesting aspect is that even data with a pseudonym are not considered as personal data as long as technical and organisational measures are applied such that re-identification is not possible. With this definition, data can be used in various research projects and can be connected across time series (RatSWD, 2015).

### **Research with sensitive data in a legal grey area**

Personalised medicine is one of the large new research areas for which the use of sensitive data is essential. It is supported by the research programmes of the EU and also via research grants within Germany. Personalised medicine as well as “enhancing the use of databases and electronic health records as data sources for trials and knowledge transfer” is promoted by the European Research Program Horizon 2020 (European Commission, 30.11.2011) and is also addressed in numerous other calls (Horizon 2020: Work Programme 2016-2017, 2016). In addition, the German Government is financing personalised and individualised medicine via the German *Gesundheitsrahmenprogramm (Framework for Health)* (BMBF, 2010).

However, personalised medicine depends in many cases on genetic analyses which make it possible to estimate which therapies could have an effect on humans due to their genetic disposition (see Schaar, P., 2016, p. 33). The GDPR defines genetic data in Article 4, Paragraph 13 as follows: “‘genetic data’ means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question” (GDPR, art. 4, para. 13).

This means – at least if they are gathered in detail – that genetic data in principle cannot be anonymised, because the information which they contain are per se personal (see Hardenberg, 2014, p. 117). Genetic data are unique even if all other identifiable attributes are deleted, since it is in principle possible to connect them to the person to whom they belong (Arning,

Claerhout, Egermann, Forgó, & Krügel, 2011; Gymrek, McGuire, Golan, Halperin, & Erlich, 2013). Therefore genome research, and thus also personalised medicine, is inherently associated with risk in terms of data protection. According to Article 9 of the GDPR, particularly sensitive data can be collected and processed as long as the individual agrees, or if they are collected and processed for purposes of general healthcare, for example, in the context of scientific projects as well as for “studies conducted in the public interest in the area of public health” (GDPR, recital 53).

### **Open access and big data allowed but not well-defined**

The expectations of acquiring new knowledge by merging and analyzing huge amounts of data are high. The explanatory power increases if scientific questions can be pursued across multiple studies. Moreover, it is in the spirit of science if results which are obtained by research projects financed by the public are available for further research questions and for reanalysis. Open access or open science are therefore supported and now even required by various institutions. The European Commission intends to introduce an experimental phase for the open use of scientific data (Horizon 2020: Work Programme 2016–2017, 2016).<sup>11</sup>

The guidelines for the research programs of the German Federal Ministry of Education and Research and the German Research Foundation (DFG) also increasingly require open access not only for publications but also for the data collected. With regard to big data, there are approaches involving the merging of scientific data from research studies with data from other sources such as health or social insurance. The European Regulation assumes that there is an added value for scientific insight into illnesses and social circumstances, therefore and “in order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.” (GDPR, recital 157)

The GDPR does not make clear statements regarding the merging of data. As long as data are completely anonymised or pseudonymised in such a way that a person can no longer be identified, there is probably no risk for the participants of scientific studies and also no

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<sup>11</sup> “A novelty in Horizon 2020 is the Pilot on Open Research Data, which aims to improve and maximise access to and reuse of research data generated by projects. While certain Work Programme parts and calls have been explicitly identified to participate in the Pilot on Open Research Data, individual projects funded under the other Work Programme parts and calls can choose to participate in the Pilot on a voluntary basis. Participating projects will be required to develop a Data Management Plan (DMP), in which they will specify what data the project will generate, whether and how it will be exploited or made accessible for verification and reuse, and how it will be curated and preserved.” (Horizon 2020: Work Programme 2016–2017, 2016, p.6)

contradiction to the data protection regulations. Technical measures should “ensure that by default personal data are not made accessible without the individual's intervention to an indefinite number of natural persons.” (GDPR, art. 25, para. 2) More or less automated access to mass data or their analysis with a “joker request”, by which multiple datasets which are homogeneous in certain aspects can be selected, will not be possible.

However, the question of how one can deal with “open access” or “scientific use” for genetic data remains unresolved. At the same time, not just medical research questions, but also questions with relevance to the social sciences are becoming more important, for instance regarding the educational attainment or the genetic conditions for well-being (Okbay, Baselmans et al., 2016; Okbay, Beauchamp et al., 2016; Rietveld et al., 2013). Data from various research projects have already been merged within international biobanks (e.g. GERA, n.d.; UK Biobank Limited, n.d.) in order to obtain results about genetic disposition, because patterns and relationships can only be identified on the basis of more than 100.000 observations. However, the problem is that genetic data – also according to the deliberations of the European Council – are personal data (see above). They are in principle re-identifiable and therefore the question arises as to whether they should be transferred to biobanks with far-reaching usage by several data users. Also the implementation of the “right to be forgotten” (GDPR, art. 17) presents a real challenge for this category of data due to the re-identification possibilities, which in the future will presumably become technically more and more feasible. Although it is possible to allow the transfer of genetic data to biobanks with the informed consent of the participants of scientific studies, it is still unclear how the civil rights of the participants can really be protected. For example, some biobanks – such as the UK biobank – place no restrictions on commercial usage. Moreover, it has not been empirically tested how well-protected the data are against re-identification and the merging with other information.

### **Outlook: Specific implementation open**

Overall, it can be concluded that the GDPR is vague with regard to precise statements on the usage of new technologies and big data processing. In this respect it fails to live up to its own aspirations. Roßnagel and Nebel (2016, p. 6) see the biggest deficiency of the Regulation in the lack of regulation which addresses or even removes the risks resulting from the significant new challenges of modern information technology such as big data, ubiquitous computing (internet of things), cloud computing and others. The regulations are in part formulated in an abstract way and 70 flexibility clauses need to be specified on the national level (ibid., p.3).

One of the clauses concerns scientific research directly: In Article 89 the GDPR gives the Member States the opportunity to define “safeguards and derogations” for scientific research. These concern, for instance, derogations covering the right of access by the data subject (GDPR, art. 15), the right to rectification (GDPR, art. 16), the right to restriction of processing (GDPR, art. 18), and the right to object (GDPR, art. 21). Thus, the provisions can be made wider or narrower and can be specified more exactly.

The member states can also define rules for the use of especially sensitive data: “Member States should be allowed to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health. However, this should not hamper the free flow of personal data within the Union when those conditions apply to cross-border processing of such data.” (GDPR, recital 53)

Not only companies (Wytibul, 2016b), but also research institutions need to take into account the new provisions of the GDPR with respect to their research projects and need to revise the associated processes. The current debate about the introduction of ethics committees in the social sciences, in which data protection is supposed to be integrated as one aspect, has come at the right time if the opportunity is taken to integrate the new guidelines and processes.

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