



**HAL**  
open science

## Data portability in health research and biobanking: legal benchmarks for appropriate implementation

Gauthier Chassang, Tom Southerington, Olga Tzortzatou, Martin Boeckhout,  
Santa Slokenberga

### ► To cite this version:

Gauthier Chassang, Tom Southerington, Olga Tzortzatou, Martin Boeckhout, Santa Slokenberga.  
Data portability in health research and biobanking: legal benchmarks for appropriate implementation.  
European Data Protection Law Review, 2018, 4 (3), pp.296-307. 10.21552/edpl/2018/3/8 . hal-  
04590485

**HAL Id: hal-04590485**

**<https://ut3-toulouseinp.hal.science/hal-04590485>**

Submitted on 28 May 2024

**HAL** is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution - NonCommercial 4.0 International License

## Special Issue 3/2018 - Health Data, Medicine and the GDPR

**Type of submission:** Article

**Title:** Data portability in health research and biobanking: legal benchmarks for appropriate implementation

### Authors

- Gauthier Chassang – *Corresponding author*

Affiliations:

- 1-Inserm, Lawyer, UMR1027, F-31000 Toulouse, France
- 2-Université Paul Sabatier Toulouse 3, F-31062 Toulouse, France
- 3-Inserm, US13, Infrastructure Biobanques, CS ELSI Co-responsible, F-75651 Paris, France
- 4-BBMRI-ERIC, CS ELSI Expert, A-8010 Graz, Austria.

- Tom Southerington

Affiliations:

- 1-University of Turku, Project Researcher, FI-20014 Finland
- 2-Hospital District of Southwest Finland, Project Director, FI-20520 Finland
- 3-Finnish Biobank Cooperative FINBB, General Counsel, FI-20520 Finland
- 4-BBMRI-ERIC, CS ELSI Expert, A-8010 Graz, Austria

- Olga Tzortzatou

Affiliations:

- 1- Legal Consultant, Biomedical Research Foundation of the Academy of Athens, Soranou Efesiou 4, Athens, Greece
- 2- Data Consultant, Hellenic Health Foundation, Kaisareias 13, Athens, Greece
- 3- Researcher, Uppsala University, Center for Research Ethics and Bioethics, Sweden.
- 4- BBMRI-ERIC, CS ELSI Expert, A-8010 Graz, Austria

- Martin Boeckhout

Affiliations:

- 1- Julius Center for Health Sciences and Primary Care, Department of Medical Humanities, University Medical Center Utrecht, Utrecht, The Netherlands

- Santa Slokenberga

Affiliations:

- 1- Postdoctoral fellow, Lund University, Faculty of Law, Sweden
- 2- Researcher, Uppsala University, Center for Research Ethics and Bioethics, Sweden
- 3- Lecturer, Riga Stradins University, Faculty of Law, Latvia

## **Abstract**

This paper examines the content of data portability right (I), operationalization of data portability in health research context and related challenges (II) by considering both GDPR provisions and special Guidelines from the European Data Protection Board (EDPB; ex-Article 29 Data Protection Working Party or WP29). We provide in depth analysis of the provisions and tables for easing the identification of potential implementation of data portability in health research contexts.

## **Introduction**

Article 20 of the General Data Protection Regulation<sup>1</sup> (GDPR) created a new data subject's right to data portability.<sup>2</sup> The nucleus of this right is that the data subject has the right to receive the personal data that have been provided to a controller, in a structured, commonly used and machine-readable format and has the right to transmit those data to another controller without hindrances, providing conditions set forth in Article 20 GDPR are met. For biobanking, and more generally health research this right brings along considerable amount of ambiguity, and thus also uncertainties about how, if at all data portability could be carried out and how it could impact research, given the number of interests at stake. Understanding of this requirement, however, is crucial in order to ensure that researchers and biobankers acting in the capacity of controllers meet the GDPR requirements that are placed on them. This paper examines the concept and content of this right, its relationship with other provisions of the GDPR (I), and analyses special Guidelines from the European Data Protection Board (EDPB; ex-Article 29 Data Protection Working Party or WP29), operationalization of data portability in health research context and related challenges (II).

### **I. The right to data portability**

#### **1. Conceptual analysis of the right to portability**

Data portability falls within the scope of fundamental rights protected by the Charter of Fundamental Rights of the European Union. Under Article 8.2 personal data access is part of the

---

<sup>1</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) (GDPR), OJEU L 119/1, 4 May 2016.

<sup>2</sup> The right to data portability is a new right proposed by the European Commission in its 2012 proposal and is now enshrined in Article 20 of the GDPR. See Proposal for a Regulation 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 (General Data Protection Regulation), COM(2012) 11 final, 2012/0011 (COD), Brussels 25 January 2012. Article 18.

fundamental right of data protection.<sup>3</sup> Data portability extends the pre-existing right to access personal data as inscribed both in the previous Directive 95/46/EC and in Article 15 of the GDPR. The idea of reinforcing personal data access in a digital environment by creating a new right for data subjects has been continuously supported by the other EU institutions throughout the legislative process. Despite of a strong link between the right to access and to portability, they considerably differ from each other, as also stated by the European Data Protection Board (EDPB - named WP29 at that time) in their Guidelines on data portability.<sup>4</sup> It is not only a mean to improve access to and accessibility of the personal data and an efficient means to improve personal control over personal data by empowering data subjects regarding data flows and (re)uses, but it is also expected to be a data economy boosting tool supporting innovation in information and communication technologies (ICT) through facilitating data subject's choice, data exchanges and usage optimisation.<sup>5</sup>

Data portability entails a data subject's right to receive personal data that this subject has provided to a controller, in a structured, commonly used, machine-readable and interoperable format, and to transmit or have it directly transmitted to another controller. This way, the GDPR encourages data controllers to develop interoperable formats that enable data portability.<sup>6</sup> The right to data portability allows the data subject, first, to get a copy of the personal data processed and/or, secondly, the right to transmit that data to another controller or to have the initial controller to transmit the data directly, without hindrance, to a new data controller chosen by the data subject. Therefore, the right to personal data portability can be viewed as a bi-dimensional right with vertical (get a copy) and horizontal (transmit or ask for transmission) applications based on data subject's free and autonomous decision. Authors like Paul De Hart et al. count three dimensions or arms, but the right to have data transmitted is not separate from the rights to receive and transmit.<sup>7</sup> This new right supports, even if it doesn't always ensure, an individual right for the data subject to reuse the concerned data with third party controllers, for the original processing purposes or for other purposes. The following figure provides an overview of the general features of this right as derives from the GDPR.

---

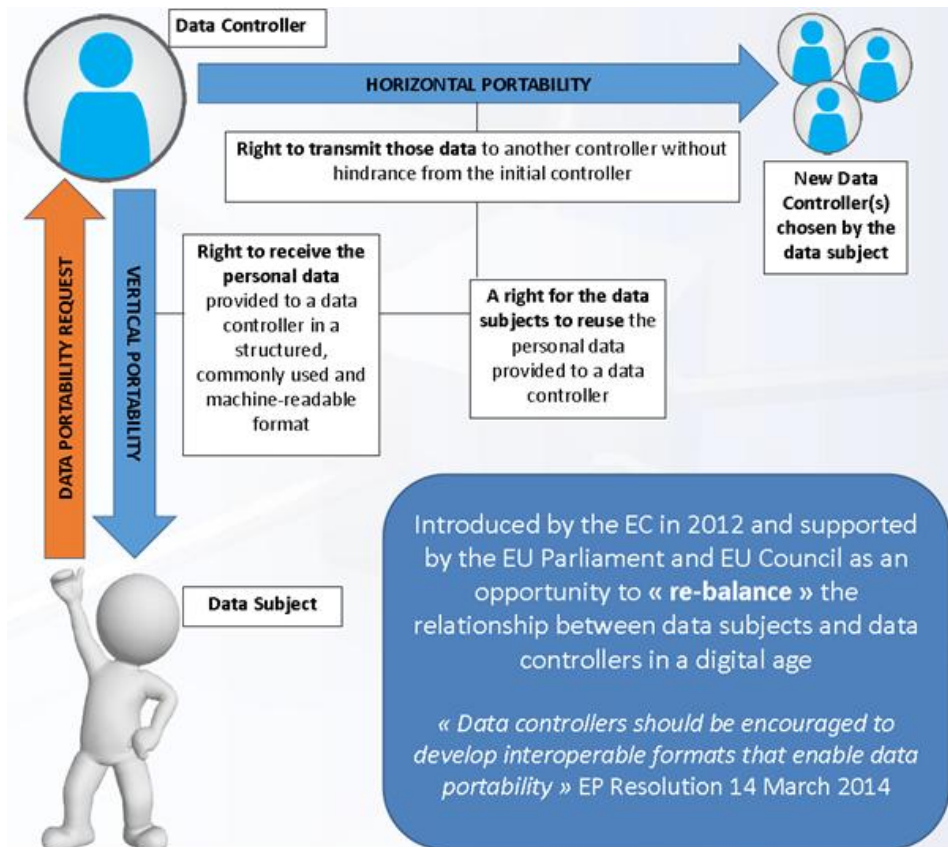
<sup>3</sup> Charter of Fundamental Rights of the European Union (2000/C 364/01), JO C 364/1, 18 December 2000.

<sup>4</sup> WP29 (Article 29 Data Protection Working party, now the European Data Protection Board). Guidelines on the right to data portability. WP 242 rev.01. Adopted on 13 December 2016. As last revised and adopted on 5 April 2017. Executive summary p.3.

<sup>5</sup> European Data Protection Supervisor (EDPS), Opinion 9/2016 on Personal Information Management Systems. Towards more user empowerment in managing and processing personal data, 20 October 2016, in particular p.3 and 9.

<sup>6</sup> Recital 68 of the GDPR.

<sup>7</sup> Paul De Hart et al, 'The right to data portability in the GDPR: Towards user-centric interoperability of digital services' Computer Law & Security Review (2018).



**Figure 1. Overview of the personal data portability right in the GDPR**

The relationship between the right to data portability and the right to access provided under Article 15 (in particular under 15(3)), are not very clear within the GDPR, which complexifies the reading of the law and could create legal uncertainties. On the top of that, the specific provisions of Article 89 of the GDPR regarding processing for scientific research and archiving purposes in the public interest shall also be considered. In the following section we provide keys for understanding the complex interactions between these provisions.

## 2. Comparison with Article 15 on right of access

Although the right to access and the right to data portability are two separate rights in the GDPR, there is a considerable overlap between these rights in practice. Article 15 applies to all personal data that the data subject has provided, but also to other personal data and other data than personal data. It applies to data processed based on any legal bases, not just consent and contract. The right of access includes the right to obtain a copy of the personal data undergoing processing. It does not in itself entail any rights regarding reuse of that data, such as the right to transmit it or have it transmitted, but once the data has been obtained, the data subject is free to transfer it to another party, unless there are specific legal impediments that restrict the transfer,

such as the original controller’s intellectual property rights. In the context of data portability, the initial controller would have to reprocess the data in order to allow reuses, so that issues related to intellectual property be resolved before the data be communicated to the data subject or transmitted to another controller.<sup>8</sup> On the other hand, the right to data portability is not completely without reservations either. Table 1 illustrates the similarities and differences between Articles 15 and 20.

	<b>Article 20 - data portability</b>	<b>Article 15 – right of access</b>
<b>Right to obtain copy of personal data</b>	Yes, but limited to ‘raw’ personal data provided by data subject him or herself and processed by automatic means based on consent or contract. Further, the right is not applicable to ‘processing necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller’ 20(1), 20(3)	Yes, it covers all personal data related to the data subject and it not limited by the bases of processing. 15(3)  Article 15 covers also many other types of data related to the processing. 15(1), 15(2)
<b>Terms or limitations from controller for obtaining data</b>	No, the personal data is to be provided ‘without hindrance’ from the controller <sup>9</sup> . An exception could be situations, where the limitations in Article 20(4) apply (see below). <sup>10</sup>	Potentially. The data is to be provided initially free of charge, but ‘further requests’ may be subject to a reasonable fee based on administrative costs. Limitations on other conditions are not mentioned

<sup>8</sup> See note 4 p.12 and 17.

<sup>9</sup> WP29 states that these hindrances could be ‘any legal, technical or financial obstacles placed by data controller in order to refrain or slow down access, transmission or reuse by the data subject or by another data controller’. WP 242 rev. 01, p.15.

<sup>10</sup> WP29 also acknowledges the possibility of limiting access based on Article 20(4), and states that the controller must ‘justify why such obstacles would be legitimate and why they do not constitute a hindrance in the meaning of Article 20(1)’. WP 242 rev. 01, p.15. This could be challenging, trying to argue that an obstacle is not a hindrance. Alternatively, the interpretation could be that when Article 20(4) overrides 20(1), then, rather than refusing the request altogether, the controller could offer a more limited right instead to retain some rights of data subjects, even if such ‘in-between-right’ of portability with hindrances is not as such recognised in the GDPR.

		in GDPR, but such cannot be introduced, because the right is absolute, unless the limitations in Article 15(4) apply (see below), and data could not be offered at all without conflict of rights. <sup>11</sup>
<b>Form/format in which data is to be provided</b>	‘Structured, commonly used and machine readable format’ 20(1)	‘Commonly used electronic form’, if the data subject made the request by electronic means, unless the data subject requests another form 15(2)
<b>Right to transmit the personal data to another controller</b>	Yes, with the right to have the controller transmit the data directly to another controller, if technically feasible 20(1), 20(2)	Not explicitly covered in the article, but possible, unless limited by for example by controller’s intellectual property rights or other legal impediments. No specific right to have data transmitted directly, even if technically feasible, but this might still be possible by appointing the receiving party as the agent/representative authorized to receive the data on the data subject’s behalf.
<b>Limited by the rights and freedoms of others</b>	Yes 20(4)	Yes 15(4)

<sup>11</sup> Attaching conditions for data access (whether under Article 20 or 15) instead of barring access on the basis of subparagraph 4 would be a data subject friendly approach, but it could also be risky for the controller, even if justified and used bona fide. It could expose the controller to allegations of breach from the data subjects and the data protection authorities, who could argue that data should have been provided without hindrance. See also the previous note.

<b>Potential Union or Member State law derogations under Article 89</b>	Yes, but only for archiving purposes in the public interest 89(3)	Yes, derogations are possible for scientific or historical research purposes, for statistical purposes and for archiving purposes in the public interest 89(2), 89(3)
---	---	---

**Table 1. Comparison of Articles 20 and 15 GDPR.**

Article 20 largely provides what is in practice a subset of the rights provided in Article 15, both in terms of personal data that is subject to the right and the circumstances in which the right applies (the legal bases and type of processing). As one would expect, where Article 20 may actually provide additional rights with the specifically stipulated right to transmit data (or have them directly transmitted horizontally from initial controller) to another controller ‘without hindrance’ from the original controller. Situations where you can transmit data obtained under Article 15(3) should presumably be more narrow, as the right in itself is about access and stays silent on what you can do with the data. Otherwise the specific right of portability would not add anything to what was already there. Another case would be all circumstances where the application of Article 15(3) is excluded while Article 20 continues to apply. The interpretation of the articles will have an impact on the differences between these rights. There will be room for interpretation in ‘without hindrance from the controller’ and in the limitations valid under Articles 20(3), 20(4) and 15(4). The applicable legal bases may not always be entirely clear, but perhaps also not subject to much interpretation. The controller should basically pick an applicable one and stick with it<sup>12</sup>, which will then also define, whether or not the Article 20 applies. The interpretation of what is considered as data provided by the data subject and thus subject to Article 20 could vary considerably and thus have a great impact, even to the extent that the set of personal data subject to Article 15(3) and 20(1) could in individual cases become the same.

### **3. No derogations to data portability in research under Article 89**

Scientific health research and biobanks activities are data-driven and highly depend on the processing of personal data,<sup>13</sup> in particular sensitive personal data<sup>14</sup> (including among others<sup>15</sup> personal health,<sup>16</sup> genetic,<sup>17</sup> or biometric data<sup>18</sup>). According to the GDPR recitals, ‘the processing

<sup>12</sup> See for example WP259 rev 01, ‘Guidelines on Consent under Regulation 2016/679’ p.23.

<sup>13</sup> In accordance with the principles under Article 6 of the GDPR.

<sup>14</sup> In accordance with the principles under Article 9 of the GDPR.

<sup>15</sup> Article 9(1) of the GDPR.

<sup>16</sup> Article 4(15) of the GDPR.

<sup>17</sup> Article 4(13) of the GDPR.



of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179(1) of the Treaty on the Functioning of European Union (TFEU) in achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health.<sup>19</sup> Research participants and donors of biological samples for research uses are entitled, as data subjects, to enjoy the rights afforded by the GDPR, including, as a main rule, the personal data portability right.

Nevertheless, the GDPR sets out a number of rights for data subjects whose relevance to health research and biobanking<sup>20</sup> could diverge in different EU Member States due to derogations which Article 89 of the GDPR allows for.

Pursuant to Article 89(2) of the GDPR, for research and biobanking purposes, data subject's right of access (Article 15), right to rectification (Article 16), right to restriction of processing (Article 18), and right to object (Article 21) could be restricted, thus leaving the research participant and sample donor with a right to information (Articles 13 and 14), right to erasure (Article 17), notification entitlement (Article 33), right to data portability (Article 20), as well as providing them with the means to safeguard the remaining rights through lodging a complaint (Article 77), providing an effective judicial remedy (Article 78-79), and gaining representation and the possibility to claim compensation (Article 82). The possibility to derogate from some of the rights is subject to the safeguards mentioned in Articles 89(1) and, pursuant Article 89(2), only to the extent those rights are likely to render impossible or seriously impair the achievement of those purposes and that the derogations are necessary for the fulfilment of the purposes. This means that the exact set of rights available depends on national EU Member States' laws, which could risk causing confusion for the data subjects about the extent of protection of their processed data for biobanking and research purposes within the EU.

Despite the opposite notion<sup>21</sup> in Recital 156, Article 20 is not amongst the list of articles that could be subject to derogation. So it is possible that even when the whole data subjects' rights listed, including the right of access (Article 15), were excluded by national law, the data subject would still have the right to demand at least some of the data to be sent to them or even transmitted directly to a third party.

For scientific research purposes, it could be therefore argued that, data subjects are in fact

---

<sup>18</sup> Article 4(14) of the GDPR.

<sup>19</sup> Recital 159 of the GDPR.

<sup>20</sup> Biobanking can be covered by Article 89, to the extent solely for purposes covered in the article. See Chassang Gauthier, 'The impact of the EU general data protection regulation on scientific research', *ecancer* 11 709, 3 January 2017.

<sup>21</sup> Symptomatic of the difficulty to apprehend the impact of the GDPR in research context, we note that although Article 89(2) does not mention Article 20, Recital 156 mentions the possibility for Member States to provide derogations from data portability for scientific research. In this paper we analyse first the directly binding provisions of GDPR Articles.

empowered to access their data, retain a copy of them and even switch to another biobank (for example) by having data transferred to the new controller, by exercising the portability right under Article 20.<sup>22</sup> This is interesting especially if the scope of data covered by Article 20 is interpreted widely and the gap in data sets covered by Articles 20 and 15 gets narrower or is closed altogether. However, although at least a subset<sup>23</sup> of rights that are the same or very similar to those provided in Article 15(3) could survive under Article 20, the possibility to derogate from Article 15 still remains meaningful, because Article 20 will not extend to other personal data than the data provided by the data subjects based on consent or contract and processed by automatic means and because Article 15 covers also other information the data controllers are usually obliged to provide under Articles 13 and 14.

We may speculate on why Article 20 was not amongst the possible derogations under Article 89 for scientific research, but in practice we can see that some modularities and legal exceptions could apply to certain research situations, even in the absence of general derogation to Article 20 under Article 89(2) and that some access rights could survive under Article 15 even in the case of exemption to data portability. Focusing on data portability, Table 2 summarises these possibilities as well as the survivance effect of some aspects of the rights of access or portability resulting from the complex interplay of derogations to Article 15 and 20. Each situation need to be checked and justified case-by-case by the controller.

Portability types (Article 20)	Potential legal basis for relevant derogations to individual rights in research and effect on data portability (GDPR)			
	Article 89(2) regarding right of access Article 15	Article 15(4) on adverse effects on the rights of others	Article 20(3) on task carried out in the public interest	Article 20(4) on adverse effects on the rights of others
<b>Vertical portability (data access)</b>	Applies*	Not applies	Not applies**	Not applies**
<b>Horizontal portability</b>	Applies*	Applies*	Not applies	Not applies

<sup>22</sup> B.Custers, H.Ursic, Big Data and Data Reuse: a taxonomy of data reuse for balancing big data benefits and personal data protection, International Data Privacy Law, 7 January 2016, accessed 14 July 2018, <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3046774](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3046774)>

<sup>23</sup> See for example Paul De Hart et al, see note 7, p.195.

<b>(transmitting data)</b>				
<p>* Only for data meeting criteria of portability (Article 20; WP29 Guidelines) and in absence of other legal hindrances.</p> <p>** Without prejudice to the right of access to other kind of information covered by Article 15(1) when it applies.</p>				

**Table 2. Overview of the application of data portability and interactions with access right in situations of legal exceptions to Articles 15 and 20**

Because of the intimate relationship between science and personal data, a new right like data portability should be clearly delimited in its scope in order not to damage scientific researches and related infrastructures such as biobanks. Therefore, a deeper careful analysis of the criteria identified by WP29 in order to practice portability in research and biobanking is necessary.

**II. The scope of portability in research-related processing: implementation criteria**

**1. Application criteria**

The right to data portability under Article 20 applies to personal data concerning the data subject, with limitations. According to Article 11(2) it does not extend to data for which the controller no longer has the data required for identification. This could for example include pseudonymised data where the controller no longer has the key required for identification. Article 20 only applies to such pseudonymous data if it can be clearly linked to the data subject, for example with an additional identifier provided by the data subject him or herself. Data within the scope of Article 20 may include personal sensitive data such as health, genetic, biometric data.<sup>24</sup> It could also include personal data related to other data subjects. According to WP29, the individual feature of the data concerning the data subject should not be restrictively interpreted by controllers receiving portability requests. A dataset containing for example personal health data such as diagnosis or treatment information, could also include identifiable information about the physicians involved. This kind of mixed personal data can still qualify for portability, but the information on other persons could limit the receiving new controllers’ rights to process the data.<sup>25</sup> The new controller should not process the transmitted data in a way that would infringe third parties’ rights, in our example, the rights of the physicians identified through the portable dataset.

Once the basic condition about the data type is fulfilled, portability will only apply when certain additional conditions are met with:

---

<sup>24</sup> Article 4 of the GDPR.

<sup>25</sup> See note 4 p.9.

1. The data subject has provided the personal data in question to the controller, and
2. The data is processed based on consent pursuant to Article 6(1) or Article 9(2) or on contract pursuant to point (b) of Article 6(1), and
3. The processing is carried out by automated means.

Criteria 3 do not raise specific issues as most of the data processing in research and biobanking are automated. However, it seems useful to come back on the other criteria.

Regarding the criterion 1:

According to WP29, not only data that the data subject provided actively and knowingly is included within the right of data portability, but also observed information regarding the data subject's activity or behaviour.<sup>26</sup> They state that, 'to give its full value to this new right, 'provided by' should also include the observed data from the activities of users such as raw data processed by a smart meter or other types of connected objects, activity logs, history of website usage or search activities'.<sup>27</sup> This is a significant expansion of the right in comparison to the wording of Article 20, potentially going far beyond what the legislator originally planned.<sup>28</sup>

One approach for understanding what should be considered as data that the data subject has provided, is looking at other GDPR articles, especially Article 13, which applies to 'data collected from the data subject'.<sup>29</sup> 'Data collected from the data subject' could be understood to be a broader term than data 'he or she has provided' in Article 20. The latter implies action on the part of the data subject, while 'collected from' could include passivity and therefore more easily extend to for example observations on the data subject, even if also this interpretation may be a stretch (observational data is not something the data subject holds, so cannot be collected from the subject, even if it is data on or about him). Under Article 13, if data is collected from the data subject, the data subject must without exception be provided with certain information 'at the time when data are obtained'. It seems clear that in cases of data gathered by observing the data subject, for example as part of automated traffic surveillance, it is not always possible to provide the information as required by Article 13. Providing the data 'at the time' may be impossible, or it may defeat the purpose of the processing - an especially relevant concern in certain types of scientific research, because providing information can affect what is being observed and thus the study results. In this light, at least when the observation is not done in circumstances that enable providing information 'at the time', whether for practical or other

---

<sup>26</sup> WP 242 rev.01, p.9.

<sup>27</sup> Ibid, p.9-10.

<sup>28</sup> See for example <<https://iapp.org/news/a/european-commission-experts-uneasy-over-wp29-data-portability-interpretation-1/>> accessed on 14 July 2018.

<sup>29</sup> Article 14 of the GDPR. The authors acknowledge that the GDPR is a result of several compromises and a long and multifaceted drafting process, which means that the integrity and internal logic of the GDPR and the relying only on the words chosen for each article and the recitals may not always suffice to understand the rules. Identical topics have been approached with different terms in different articles, word-by-word interpretation may lead to absurdities, and so on. By interpretation one should aim for a functional and harmonious system of rules.

reasons, the ‘data collected from the data subject’ should be interpreted as excluding observational data.<sup>30</sup> If ‘data gathered from the data subject’ excludes observational data, it does not seem warranted to consider it as data ‘he or she has provided’. This could be what also the WP29 had in mind: not including all kinds of observational data as data ‘he or she has provided’, but only observational data collected in certain circumstances, when there is a close enough contact between the controller and the data subject being observed, the kind of contact that also enables providing information to the data subjects at the time of collection. Even this is a broad interpretation.

WP29 distinguishes observational data from inferred or derived data which are ‘created by the data controller on the basis of the data provided by the data subject’, such as algorithmic results.<sup>31</sup> Inferred or derived data are not considered to be provided by the data subject him or herself and thus not subject to Article 20.<sup>32</sup> The frontier between ‘observed’ and ‘inferred’ data can be thin and deserves further attention in the context of research. For example, in genetic research, the data subject will usually provide biological samples from which raw genetic data is obtained and processed by the researchers. In this situation, one could (but perhaps should not) interpret the GDPR as providing portability right on the genetic sequence as data provided by the data subject, if processed under consent. Any data then generated from the sequence during the research would be considered as inferred, created through an additional layer of processing by the data controller. In research where the data subject provides access to already inferred data, such as medical records for example, they will have data portability rights on them. To maintain efficient data portability the data controller needs to in advance filter data which are portable from those which are not, unless they are prepared to share data more widely than what is mandatory under the GDPR.<sup>33</sup> In brief, a case-by-case analysis of the qualification of observed/derived data is necessary to ensure proper implementation of data portability in research.

Regarding the criterion 2:

This criterion about data provided on the basis of consent or on a contract is particularly interesting in the field of scientific research.

For example clinical trials and studies falling under the scope of the EU Clinical Trial Regulation (CTR)<sup>34</sup> in the vast majority of cases use written informed consent as a precondition of

---

<sup>30</sup> In these cases Article 14 applies with its exceptions as to if and when information needs to be provided.

<sup>31</sup> WP242 rev.01, p.10.

<sup>32</sup> While they could be concerned under Article 15.

<sup>33</sup> Disregarding mandatory legal rights, ethical guidelines favor letting subjects know general research results, notably through publications, and in some cases also individual research results such as clinically validated incidental findings. These rights are also covered in some international legal instruments, see the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasbourg, 25 January 2005. Article 26 which applies to interventional research, and Article 10 of the Convention itself.

<sup>34</sup> Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. OJ L 158, 27 May 2014, p.1–76.

interventional research involving human beings, this being aligned with major ethical guidelines such as the Declaration of Helsinki.<sup>35</sup> At least currently, the consent forms typically include also consent for processing personal data. In these cases, in the absence of excuses under Articles 11(2), 20(3) or 20(4), data subjects are entitled to data portability for any data they provide for the research.<sup>36</sup> In other research contexts, data could be collected and processed on the basis of ‘informed non-opposition’ mechanisms under applicable Member States laws. Because the GDPR, as interpreted by the WP29, only considers opt-in consent as valid consent,<sup>37</sup> opt-out mechanisms do not qualify under criteria 2, and some other legal basis needs to apply for processing to be legitimate.<sup>38</sup>

Regarding data provided in the context of a contract (or during a pre-contractual phase), this could concern situations where research is based on opt-out and/or attached to commercial offer (eg Direct to consumer offers; e-devices).

## 2. Exclusion criteria

In addition to the exclusion criteria identified by interpreting a contrario the application criteria related to the nature of the data and the conditions related to their collection, and the exception in Article 11(2), the right to data portability is limited by:

1. Article 20(3) saying that the right to portability shall not apply to processing necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.
2. Article 20(4), according to which the right to receive and transfer data shall not adversely affect the rights and freedoms of others.

Regarding the criterion 1:

To figure out what is a task carried out in the public interest is not easy because the notion relies on EU or Member States law explicitly naming a task as of public interest. The GDPR provides some examples which could, to some extent, cover research activities, but it doesn’t link the notion to research activities while it does link it directly to archiving<sup>39</sup>. This could mean that any scientific, statistical or historical research must prove to pursue an identified public interest. Whether intentionally or inadvertently, there is no more presumption of public interest for

---

<sup>35</sup> WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

<sup>36</sup> Under the GDPR, this does not cover individual research results, even if such data may by ethical guidelines require disclosure (see section II.1 below).

<sup>37</sup> See WP29 Guidelines on Consent under Regulation 2016/679, wp 259 rev.01, 16 April 2018, p.16.

<sup>38</sup> The GDPR does not expressly rule over opt-in and opt-out. Under Article 4 consent is ‘any freely given, specific, informed and unambiguous indication of the data subject’s wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her’. In accordance with WP29 and Recital 32, ‘silence, pre-ticked boxes or inactivity should not therefore constitute consent.’

<sup>39</sup> This could be because not all archiving should be entitled to special treatment, while scientific research always enjoys protection by fundamental rights and freedoms.

research activities, as there was in the previous Directive 95/46/EC, which mentioned in Recital 34 that '[...] areas such as public health and social protection - especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system - scientific research and government statistics' were considered as 'important reasons of public interest'. In the GDPR, the situation is less clear, Article 9 referring successively to 'reasons of substantial public interest' (Article 9(2)(g)) and to 'reasons of public interest' (Article 9(2)(i) and (j)) separately from scientific research. While the 'reasons of substantial public interest' are not detailed, 'reasons of public interest' explicitly include processing 'in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.'<sup>40</sup> 'The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific processing along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles.'<sup>41</sup> A recent ruling from the European Court of Justice reinstates such conditions, in particular the proportionality of the national provisions of public interest basing the derogatory processing and the existence of efficient individuals' right to lodge a complaint.<sup>42</sup> Therefore, any research processing carried out with sensitive data in these exceptional contexts will be based on the related above-mentioned special Article 9 paragraphs, not on the usual research legal ground of Article 9(2)(j). The processing of personal data for scientific purposes should also comply with other relevant legislation such as on clinical trials, which could directly include public interest activities and related derogations.

Recital 158 about archiving states that 'public authorities or public or private bodies that hold records of public interest should be services which, pursuant to Union or Member State law, have a legal obligation to acquire, preserve, appraise, arrange, describe, communicate, promote, disseminate and provide access to records of enduring value for general public interest.' These criteria can also be relevant for scientific research activities.

Research carried out in the public interest will be exempt from data portability. In practice, the controller shall be able to demonstrate the existence of this public interest overriding the data subject's interests, fundamental rights and freedoms. Member States could even codify that scientific research is deemed to be carried out in the public interest in relation to them, confirming legal bases for processing under Article 6(1)(e) in accordance with Article 6(3) and

---

<sup>40</sup> Article 9(2)(i) of the GDPR.

<sup>41</sup> Recital 156. See also Article 6(3) of the GDPR.

<sup>42</sup> *Puskar v Finance Directorate of the Slovak Republic*, Case C-73/16, 27 September 2017.

potentially also under Article 9(2)(g).<sup>43</sup> Processing could in such cases be based on these alternative legal grounds, but scientists could still rather rely on consent as the legal basis for processing. Nevertheless, Article 20 would continue to not apply, when the research is carried out in the public interest. Some research may also be performed ‘in the exercise of official authority’, for example by national health institutes collecting nationwide data. Again, the right to data portability would not apply. For each research project or biobanking activity the data controller has to check if the criteria are met.

Regarding the criterion 2:

Intuitively it feels right that one should be entitled to data one has provided him or herself, and to dispose of it as one pleases, but the more data we read into this category of ‘my data’, the more we move away from data we’ve actually actively provided and the more burdensome this right may become to comply with to the scientists.

Even when there is no possibility to derogate from Article 20 under Article 89 for scientific research, it may in some cases be possible to invoke Article 20(4) to reject a request under Article 20 for reasons specific to the particular scientific research project. These occasions should presumably be rare. It is not easy to envision, when the release (or return) of data provided by the data subject her or himself could be in conflict with the rights of the controller or a third party. However, the broader the interpretation of what is considered as data provided by the data subject, the more there are possibilities that releasing the data could conflict with other rights of the controller or other parties. For example, observations could include information concerning several data subjects at the same time and providing the data to one of them, especially for the purposes of being transmitted on-wards, could infringe their rights. A collection of data can also be subject to the controller’s intellectual property rights or it could reveal sensitive facts about the research project or its unpublished results, or for example the applied data processing methods.

When interpreting the limitation under 20(4), it should be taken into account, that unlike in the case of the right of access, the main purpose of the right to data portability is to enable transmitting the data on-wards, not just to provide access to the data subject him- or herself. For the data controller to be able to make an informed decision about the data request in case of data relevant for its own or third parties’ rights, the data subject should inform the controller of the intended receiver, although under the law they have no obligation to do so. In case of doubt, the controllers may be more conscious about releasing the requested data, when it relates to third parties or potentially affects the controller’s own rights.

---

<sup>43</sup> For example the Finnish government bill 9/2018 for the new Finnish Data Protection Act to complement the GDPR proposes that processing would be legal under Article 6(1) subparagraph (e), if the processing is necessary for scientific or historical research or for statistical purposes and is proportionate to the objective pursued in the public interest.



### 3. Specific concerns, special themes and topics for further research

While data portability application will presumably be limited in scientific research it seems interesting to support further research about the impact of such a right in the field of scientific research, not only in legal terms but also regarding research ethics. Indeed, data portability could have several potential positive effects for research. Data portability could create some unique research opportunities for researchers. They could, for example, arm their research subjects with wearable devices or ask them to use certain services, and after a while ask the subjects to request from the device manufacturers or service providers that their data be transmitted to the research institution. The data produced by the devices or as part of the services monitoring the users' behaviours (based on consent or contract) would become research data, saving the researchers a lot of work, essentially enabling them to use the service provider's resources to gather the research data. The researchers could even post an open recruitment ad: anyone interested in getting more information about their health and using any kind of health device, app or service, please write to your service provider and ask them to send all data concerning you to our research institution. As presented earlier, Article 15 indirectly enables the same, with more data and no limitation to legal bases of processing, but it may more readily be rejected based on the controller's rights, for example, while in Article 20 the 'without hindrance from the controller' and the explicit right to transmit onwards creates more pressure to override the controllers' and potentially also third parties' rights and interests. Data portability could also bring added value to citizen science and open science development, thus reaching European Commission's ambitions to foster Open Science<sup>44</sup> and FAIR guiding principles for research data stewardship, with FAIR standing for Findability, Accessibility, Interoperability and Reusability.<sup>45</sup> Beside the legal possibilities offered to individuals to have a more proactive role in research through individual portable data stewardship, the technical modalities attached to this right in order to provide comprehensive, interoperable and reusable data for portability purposes could ease the creation of technical standards for data sharing. More research is also needed to envisage the articulation between data portability and existing ethical guidelines applied in biomedical research in order to identify potential synergies, (false-)positive and (false-)negative effects of portability in situations where such right is applied. While this right could have significant benefits in certain research contexts it is also bringing concerns and risks which should also be scrutinised. Concerns about the fluctuant scope of personal data portability creating legal uncertainties in the

---

<sup>44</sup> See for example European Commission, Open Innovation, Open Science, Open to the World - a Vision for Europe (DG Research and Innovation 2016) <<https://bookshop.europa.eu/en/open-innovation-open-science-open-to-the-world-pbKI0416263/>> accessed 14 July 2018. Also, Horizon Europe (Framework Programme for Research and Innovation) – Proposal for a Regulation COM(2018) 435, 7 June 2018 <[https://ec.europa.eu/commission/sites/beta-political/files/budget-may2018-horizon-europe-regulation\\_en.pdf](https://ec.europa.eu/commission/sites/beta-political/files/budget-may2018-horizon-europe-regulation_en.pdf)> accessed 14 July 2018.

<sup>45</sup> Mons B and others, 'Cloudy, Increasingly FAIR; Revisiting the FAIR Data Guiding Principles for the European Open Science Cloud' (2017) 37 Information Services & Use 49; Wilkinson MD and others, 'The FAIR Guiding Principles for Scientific Data Management and Stewardship' (2016) 3 Scientific Data 160018; Boeckhout M, Zielhuis GA and Bredenoord AL, 'The FAIR Guiding Principles for Data Stewardship: Fair Enough?' [2018] European Journal of Human Genetics 1.

field of research, but also about the technical feasibility and economic impact of data portability, about effects on competition and intellectual property protection, are some examples of challenges put by this new right. Other concerns emerge from transfers of responsibility operated within the implementation of data portability. Indeed, where data portability is practiced, in any cases, the initial controller is responsible for informing the data subject about the existence of data portability right and types of data concerned before the processing, and to answer to related individual's request. He is in charge of gathering the relevant data from processors, of formatting the data in portability conditions and of ensuring secure data communication in one month (up to three months from original request with justification). The initial controller acts on request and is not responsible of the further uses of the data decided by the data subject. In horizontal portability, data protection-related responsibilities are transferred to the secondary controller which has to comply with GDPR, in particular with lawfulness and data minimisation principles. In vertical portability, the responsibilities are transferred to the data subject. This latter situation is potentially risky, in particular where complex sensitive data would be at stake (eg genetic data), and could lead to data misinterpretation or misuses in the absence of appropriate counselling. This risk is reinforced by the absence of an obligation for the initial data controller to check the quality of the data requested and by the fact that data subject could be let alone regarding the management of the security of the data storage service they would choose or use. Further studies and risk/benefit assessments related to the practice of data portability in scientific research will be necessary in order to ensure proper implementation preserving fundamental rights and freedoms of both individuals and researchers acting in the public interest.

### **III. Conclusions**

As we have covered, Article 20 applies only to certain personal data processed on certain bases and in a certain way. Most scientific research projects presumably use automatic means of processing, so that requirement is fulfilled, but it doesn't always require data that is provided by the data subject him or herself. And, scientific research is not always based on consent and is probably very rarely based on contract with the data subject. It is also possible for the Member States nationally legislate on some of the legal bases, which may lead to scientific research increasingly being based on other grounds than consent in some countries, especially 'public interest' under Article 6(1) point (e) and in case of special category data the appropriate base under Article 9(2), especially subparagraph g, i or j. In addition, research may fall under the exceptions under Articles 11(2), 20(3) and 20(4). Therefore, Article 20 does not and will not apply to all research projects, and its application will in practice vary between scientific research projects and between the Member States.