

## Comment

on the draft by the European Parliament regarding A regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation, referred to hereinafter as the GDPR)

taking into account the draft by the European Commission

*[ENGLISH TRANSLATION]*

Comment by

TMF – Technologie- und Methodenplattform für die vernetzte  
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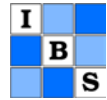
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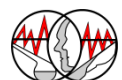
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# Protecting citizens – enabling research

## Foreword

Protecting citizens, their privacy and personal data from being misused or disclosed is of public concern throughout Europe. This also applies to patients' and test persons' data in biomedical research. The research world and scientists themselves have a major interest in consistently protecting data and employing ethically acceptable processes. Because any infringement or misuse of data that becomes known would shatter citizens' trust in research and have a severe impact on people's willingness to take part in medical research projects. Therefore, the EU Commission's and the European Parliament's intention to establish and harmonise compulsory legal standards regarding data protection, technical and organisation specifications for handling personal data and legal processes to check and monitor these specifications in Europe, are in principle in the interests of biomedical research and to be welcomed by the sector. However, in pursuing this goal, it is equally important that regulations and procedures that serve to protect citizens do not unintentionally hamper or prevent biomedical research that is in fact in their interests. Even if not trivial in individual cases, the goal is in point of fact to protect citizens and enable biomedical research at the same time.

As a result, this comment from medical science facilities in Germany reflects the position of the non-commercial biomedical research sector regarding the European Parliament's draft law of 12 March 2014, based on the recommendations and rulings of the Committee on Civil Liberties, Justice and Home Affairs (LIBE) of January 2013 and 21 October 2013, also taking into account the draft of the European Commission of 25 January 2012. Consequently, the comment focuses on the sections of the planned data-protection legislation in the EU which directly relate to biomedical research. Any other issues, such as for example aspects relating to European law and the EU Commission's regulatory competence, which are also the subject of critical debate, will not be discussed. The comment will tie in with comments already made by medical-science organisations, in particular the Europe-wide initiative by the British Wellcome Trust<sup>1</sup> which is also supported by several German research facilities. The

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<sup>1</sup>[http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy\\_communications/documents/web\\_document/WTP055584.pdf](http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/WTP055584.pdf)

signatories to this comment essentially agree with the Wellcome Trust's statement. Furthermore, the comment looks in detail at a) whether certain sections of the planned EU-GDPR will make biomedical research easier or harder in the legal framework or in practical legal terms, b) whether the goal of cross-border harmonisation of data-protection practices will be achieved as regards biomedical research and c) whether new ambiguities will emerge due to the planned regulations which could lead to uncertainty, delay and more time-consuming clarification procedures for research projects. The purpose of the comments by experts that compare the version passed by the European Parliament and the initial draft by the EU Commission is to provide helpful stimuli for future discussions and rulings regarding European data-protection legislation. The scientific organisations that have signed this comment are asking Members of the European Parliament and the German government during future proceedings to pursue the well-being of citizens, both as regards the protection of their personal data and their demand for medical progress.

### **Summarised evaluation**

1. In principle, biomedical research welcomes the standardisation of data protection in the EU. This would make aspects relating to data-protection much easier and create more legal certainty, particularly where integrated projects at a European level are concerned. In Germany itself, if the different data-protection acts passed by individual federal states with opposing regulations in some cases and details were no longer to exist, a positive impact on research is also to be expected.
2. The adoption of a framework of provisions as regards data processing for historical or statistical purposes, as well as for scientific research purposes as set out in article 83 of the Regulation, is to be welcomed. However, how these provisions apply to other sections of the draft on research that deals with data concerning health is not clear. In particular, there is unfortunately no logic in the way in which references are made between the provisions which are crucial to biomedical research, namely art. 9 and 81 (data concerning health) on the one hand and art. 83 (research) on the other. It is very difficult to understand, even for trained lawyers, and is highly likely to be impossible for researchers. The result is uncertainty regarding the legal position, entailing a huge amount of red tape for research and in the end risks which could in some cases jeopardise projects. What research primarily needs are unambiguous rules.

3. In vital areas of the Regulation, research limitations are too narrow. In particular, biomedical and healthcare research using extensive legacy data collected while caring for patients would be very restricted, if indeed not prevented entirely. This affects in particular art. 81 and 83 of the Parliament's draft, which without weighing up the basic rights concerned (the ability of individuals to determine information passed on about themselves versus the freedom of research) precludes research without consent, even in the facility that is treating the patient.
4. The opening clause in art. 81 which stipulates very restrictive conditions for national regulations of this type might however be an option in order to specifically amend the fundamental restrictions of the Regulation via national provisions for issues relating to biomedical research and processing patient data in the healthcare system, if the opening clause were valid for all areas addressed in art. 81 and art. 83 of the Parliamentary draft. At the same time, this solution would undermine the principle of harmonisation of the legal framework which was intended and therefore the added value achievable for research due to international harmonisation.
5. The requirement in the Parliament's draft that consent to processing personal data must include references to "one or more" pre-defined purposes jeopardises the concept of broad consent. After in-depth and long public debate in Germany, broad consent has won through as a feasible option for biomedical research. This is the only way of processing innovative and pioneering research projects (e.g. in biobanks, registers and cohorts) so that they comply with the law, where the goals of which are often not predictable and are not obvious until research progresses. In return for broad consent, access to the data concerned is safeguarded by stringent procedures and the requirement for a voting procedure by an accredited ethics commission – with the goal being to provide trust-building compensatory measures. When voting on ethics, the right of individuals to decide what happens to their personal data and society's own interest in research must be weighed up on a regular basis. Outside clinical trials which are subject to the German Pharmaceuticals Act (AMG) or Medical Products Act (MPG), this procedure, already established in the research world and accepted by society, is subject solely to law that governs professions. Including it in the EU-GDPR could help to establish a Europe-wide standard regulation, independently of professional groups, which would be fair to the interests of patients, test persons and biomedical research. On the other hand, merely challenging the previously achieved consensus of broad consent would damage medical research significantly and could set it back years.

6. An EU regulation should also provide the option to weigh up freedom of research and the interests of data protection in certain cases, as is currently the case in the German Data Protection Act and the data-protection acts in the German federal states. Common practice in Germany has shown that this option is only exercised in exceptional cases and no major breach of data-protection interests is to be feared. To implement certain research projects, the option to weigh up the two arguments can be pivotal.
7. The concept of “relative personal reference” is dealt with very differently across Europe and is controversial even in Germany. This specifies that re-identifiable data can be considered totally anonymous to the body receiving it if this body has absolutely no way of linking the data its subject. There is no clear acknowledgement of this concept in the Regulation, although it would constitute a significant step towards a European-wide standardised approach to data protection.
8. In public debate about the Parliamentary draft of the EU-GDPR and the obstacles it would entail for medical research (not least in the European Parliament itself) a return to the draft of the European Commission was recommended regarding the sections concerned.<sup>2</sup> Even if from the standpoint of biomedical research this would be helpful in some cases, aspects which were already problematic in the Commission’s draft must not be overlooked.

Therefore, the blanket specification in art. 7, section 4 of the Commission’s draft appears problematic because it states that consent is not a legal basis for data processing if a significant imbalance exists between the data subjects and data controllers. This view puts the legal footing of many research projects which involve ongoing treatment of patients at risk, e.g. clinical trials, which in oncology are often very closely linked to treatment. Therefore the planned amendment in the Parliamentary draft is to be welcomed.

9. The Commission’s draft in recital 23 only has an imprecise definition of anonymous data and in art. 83 only an implicit definition of anonymised and pseudonymised data. A

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<sup>2</sup> See also the comment by the EU Commissioner Viviane Reding on 11 March 2014 in the plenary debate in the European Parliament, Strasbourg, which recommends a return to the Commission’s draft regarding processing of data relating to health (which complies with article 81 of the EU GDPR draft).  
<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20140311+ITEM-013+DOC+XML+V0//DE&language=DE>

definition of pseudonymised data was included in article 4, section 2 a of the Parliamentary draft and is to be welcomed in principle. Given the importance of both concepts for biomedical research, the addendum is however insufficient.

10. In the Commission's draft, requirements were set at an indiscriminately high level concerning documentation, preliminary checks regarding data-protection law and impact assessments of research projects which are based on data concerning health that allows conclusions to be drawn as to the identities of its subjects. As a result, in some cases the draft goes way beyond the previous regulations under German data-protection law and would not fully respect the principle of proportionality. We believe that in the case of small, short-term research projects, where the data to be processed remains in clinics treating the patients, other measures should apply regarding impact assessment and preliminary controls than for cross-facility databases and biobanks that are used for long periods of time and the purpose of which is still open. In the Parliamentary draft of the Regulation the preliminary checking procedure is at least for the most part similar to German standards and we very much welcome this fact.



## **Detailed comment on the sections in the EU-GDPR draft versions which are particularly relevant to biomedical research.**

The goal of the EU Commission's "General Data Protection Regulation" (GDPR) presented on 25 January 2012 is to standardise data-protection law throughout Europe. The previous legal framework which spawned national implementations of the 95/46/EC directive and other directives for specific areas is to be replaced by the same regulation that applies directly to all 28 EU Member States. Extensive changes to the first GDPR draft were proposed in a report by the Committee on Civil Liberties, Justice and Home Affairs (LIBE) which was presented by the report owner Jan Philipp Albrecht, MEP, in January 2013. Parts of this extensive proposal for changes were adopted in a version passed by the European Parliament's Committee on Civil Liberties, Justice and Home Affairs on 21 October 2013 which has been validated as a basis for further negotiations by the plenary of the European Parliament on 12 March 2014 by a large majority.

This comment takes into account this current version by the European Parliament, but does however go into detail about the version of the draft of a GDPR presented proactively by the EU Commission in January 2012 and scrutinises it regarding the aspects relevant to biomedical research. As a result, this comment differs from all other comments over the last few months which chiefly take a critical look at the LIBE report or the version passed by the Committee on Civil Liberties, Justice and Home Affairs in October and therefore suggest to the public that implementation of the original, unchanged draft would not be a problem for research.<sup>3</sup> Even if we concur with the majority of the arguments and findings of current comments of a research-political nature, the institutes who have commented believe that the original draft also includes provisions not yet, or only marginally highlighted in the debate until now that would have a negative impact on the practical implementation of biomedical research projects.

### **Art. 4 - Definitions**

As regards general definitions in art. 4, the Commission's draft of the GDPR does not include any definitions of anonymisation and pseudonymisation. There is merely an implicit and

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<sup>3</sup> See for example the Medical Sciences Committee Opinion Paper, "The Benefits of Personal Data Processing for Medical Sciences in the Context of Protection of Patient Privacy and Safety", May 2013, <http://www.scienceeurope.org/uploads/PublicDocumentsAndSpeeches/ScienceEuropeMedicalPaper.pdf>

imprecise definition of anonymised and pseudonymised data in art. 83, section 1. Because these two concepts are so important in research we do not believe these definitions go far enough.

Recital 23 merely states that the “principles of data protection [...] should not apply to data rendered anonymous in such a way that the data subject is no longer identifiable”. There is no clearer indication that the right to data protection does not apply to data as long as it is considered anonymous.

#### *Regarding the Parliamentary draft*

The current draft by the European Parliament has added to the original draft by the European Commission to the extent that as regards the general definitions in art. 4, section 2a, a definition of pseudonymisation will be given. We welcome this fact because pseudonymisation in research is a widespread tool with a good track record that promotes data efficiency. However, there is still no precise definition of anonymisation and therefore no clear segregation of these two concepts from one another.

However, an extensive outline of personal references was included in recital 23. For the first time, aspects were considered that had to be taken into account when assessing the ability to identify a person. Therefore, all aspects are to be considered which “may be used to create profiles of the individuals and identify them”. To do so, all objective factors such as the cost and time required must be looked at. Not only the state of the art, but also the direction in which it is likely to develop need to be looked at. Data which cannot be identified based on these criteria is considered anonymous. Data-protection principles are not to apply to this data.

We agree with this definition in principle. However, we believe that a realistic and verifiable forecast regarding how technology is likely to develop would be virtually impossible. Therefore, this criterion should be dropped. It is a problem that key definitions were made in different places in the current draft even though some of them can only be understood by distinguishing them from others. We recommend standardising these definitions and including them in art. 4 so that they are clearly distinguished from one another in order to avoid legal uncertainty at a later date. This applies in particular to the distinction between anonymous and pseudonymised data.

Currently, both in research and in other areas, significant legal uncertainty exists regarding the reliability of a “relative personal data” concept.<sup>4</sup> If relative personal data is assumed, to a sender data can be personal and not personal for the recipient at the same time. This would be the case if only the sender had information that allowed allocation of the pseudonyms to the identities of the persons concerned and the recipient had no access to this allocation. The decisive factor is now whether, in order to identify the persons concerned, merely the knowledge on the part of the recipient or other knowledge that cannot be accessed is taken into account. In the latter case, all global knowledge would have to be considered. Then the concept of personal data would be vast and we believe widened to an extent which is not permissible.

In the current version of the draft, to identify a person as set out in recital 23 all means need to be taken into account which “by the controller processing or by any other person” are likely and will probably be used to identify a person. While referring to other people could indicate that absolute personal reference must be assumed, the restriction regarding the means could be interpreted to the effect that a relative personal reference exists if a recipient (according to objective measures and when taking into account technical progress that is to be expected) will not be able to obtain access to the allocation key.

In research, technical means of rendering data pseudonymous are very important because often no personal reference is required to analyse data scientifically. However, anonymisation is often barred because this would prevent classification of follow-up data or feedback on important results to the people concerned. As part of its consultancy activities, the TMF knows of many cases of legal uncertainty regarding the legal status of pseudonymous data when the allocation data for example remains in a hospital which is protected from prosecution under criminal law.<sup>5</sup> The assessment by local business or official

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<sup>4</sup> See for example Landgericht Berlin, ruling of 31 January 2013; ref.: 57 S 87/08 (Dynamic IP-address as personal data).

<sup>5</sup> Over the past few years, the TMF’s data-protection working group has provided support on over 70 research projects and facilities regarding the implementation of data and samples under data-protection law. Support was based on the TMF’s generic data-protection concepts which were discussed for the first time in 2003 with the government and federal states’ data-protection officers at a national level. Since then, a concept for biobanks, also discussed with the data-protection officers, has been added (in 2006) and has been extended and updated to produce an in-depth guideline on data protection in medical research (2014). The current version of the guideline was unanimously adopted by the State Conference of Data-Protection Officers and the Federal States on 27 and 28 March 2014 and recommended for usage in biomedical research facilities and projects in Germany.

data-protection officers and the supervisory authorities is not standardised in this respect. In other words, this will jeopardise databases created for research for years to come.

Consequently, we urgently recommend using the current legislative initiative, defining the concept of relative personal allocation clearly and therefore generating legal certainty for biomedical research and for many other applications.

### **Art. 5 – Principles relating to personal data processing**

Article 5 describes the principles (also codified under German data-protection law) of transparency, specification of purpose, data economy, accuracy and integrity, limitation of storage periods and responsibility when processing personal data.

Regarding specifications on transparency (a), data economy (c), accuracy and integrity of data (d), restricting the storage period (e) and the responsibility for data processing, the regulations mostly correspond to the legal position defined in Germany at a government and federal state level and current research practice. Therefore, these specifications are to be supported.

The principle of limiting data processing to “specified, explicit and legitimate purposes” as stated in (b) is identical to the applicable directive (art. 6, section 1, b) and also defines the German Data Protection Act even if it is not explicitly mentioned in the first section of the act.<sup>6</sup> The fact that the wording is identical suggests that no changes should be made to legal practice which has developed based on this. However, in other places as regards the directive, additional passages concerning specification of purpose (art. 6, section 1, a and art. 9, section 2, a) could be interpreted as restrictions. Therefore, it is unfortunately unclear to what extent the previous detailed comment on “art. 29 Data Protection Working Party” of April 2013 can be maintained as an interpretation of the Regulation.<sup>7</sup> Concerning the crucial issue of how specific a purpose must be in research terms, the Working Party states: “...future research will – without more detail – usually not meet the criteria of being specific”. On the other hand, the Working Party explicitly opposed over-detailed descriptions of purposes in consent forms which act as disclaimers rather than informing people in a meaningful way. They go on to say that the level of specific purpose depends more on the

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<sup>6</sup> Gola/Schomerus, GDPR comment, 11th issue 2012, article 14, regulation 9.

<sup>7</sup> WP 203, adopted on 2 April 2013, “Opinion 03/2013 on purpose limitation”

context in question. Clarification would however be important to biomedical research, as stated further below on comments about art. 9. This is not to be expected as part of the provisions in art. 5, but art. 83 would be a good place to accommodate this clarification.

### **Art. 6 – Lawfulness of processing**

The provisions in art. 6 only appear to be relevant to research based on health data if no more specific regulations are made in art. 9. Therefore, the principles governing lawfulness of processing will be discussed in this comment on art. 9. Requirements or recommendations for changes to art. 6 also however arise for other areas of research based on some of the points discussed there.

Generally, due to the current legal system, many of the principles of lawfulness of processing are formulated in an identical, or only slightly different form, see for example article 6, paragraph 1, b and art. 9, paragraph 2, aa. These could lead to unintentional incongruences and makes the Regulation more difficult to understand.

### **Art. 7 – Consent**

Art. 7, paragraph 1 of the Commission's draft redefines the burden of proof required for consent. According to the draft, no proof has to be provided however *that* the relevant facts have actually been explained to person concerned, or *of the method* employed to do so, or *what* has been explained to the person concerned. The combination of this provision with art. 4, section 8, art. 11, art. 14 section 4 suggests that prior explanation of the facts is not a condition for consent being effective. In point of fact, explanation of the facts can be given afterwards.

In exceptional cases in medical research (i.e. for research on patients admitted as emergencies) this is necessary and already customary today. As a general rule however, this new provision would be a serious departure from the generally practised concept of informed consent customary to date. Steps such as explanation of facts at a later date and offers to continue to create transparency, for example in biobank-based research, will gain importance and must be made possible in cases where appropriate reasons are given. It is open to doubt to what extent the current wording intends this to become a rule.

Furthermore, the blanket specification in art. 7, section 4 of the Commission's draft appears problematic because it states that consent is not a legal basis if there is a significant imbalance between the data subjects and data controllers. An example of dependency is

given in recital 34 of the GDPR in the case of employees vis à vis their employers. However, it is unclear whether the unspecific wording could be applied to the relationship between patients and the doctor treating them. This would put the legal certainty of many research projects linked to the treatment of patients at risk. An example of this would be clinical trials which (particularly in oncology) are often very strongly linked to treatment. The legal certainty of many projects in healthcare research would also be at risk.

#### *Regarding the Parliamentary draft*

Therefore we welcome the amendment to paragraph 4 which drops the blanket regulation in the Commission's draft which states that consent is not legal if there is substantial imbalance between the data subject and the controller.

On the other hand, the amendment stating that consent is only legal for the period required to process personal data for the purpose given, is only acceptable if research is given the option of specifying a purpose that is more open and appropriately broad consent, as discussed regarding art. 9.

#### **Art. 9 – Special data categories**

As is the case in the applicable directive, the draft Regulation also includes special provisions regarding certain data categories which need to be classified sensitively. These include data on race, ethnic group, sex, sexual orientation, genetic makeup and health, which by their very nature are used in medical research. Therefore, art. 9 is fundamental to medical research.

Art. 9 more or less corresponds to art. 8 of the applicable directive. The following amendments/updates were included which are relevant to medical research:

Genetic and biometric data was especially included in the list of sensitive data. However, this should serve to clarify matters because under the current directive genetic data is considered data on health. As a result, recital 26 is worded in such a way that it clarifies that data on health also includes data which is based on the analysis of bodily substances.

#### *Paragraph 2*

Recital 42, which has only been altered slightly by Parliament, sets out the procedure. There are three conditions for prohibiting the processing of sensitive data: processing requires a legal basis, special precautions must be taken to protect the data and the data must be of special interest to the public. Essentially, these conditions already apply in the directive.

Recital 123a does recognise a research interest with data on health and therefore justifies that in future regulations on exceptions should be made at a national level too.

It is noticeable however that in the research clauses under German data-protection law (see article 13, section 2 and article 28 section 6) the exceptions to the prohibition on processing particularly sensitive data, based on a weighing-up of the interests of research and individuals, is not reflected in the draft Regulation. In the original Commission's draft, art. 83, section 2, b merely weighed up these interests especially with regard to publishing data in a scientific context. The exception to the prohibition in art. 9, section 2, g (see below) based on European Union law, or the law of a Member State, which in turn has to appropriately balance out public and private interests, is no replacement for a general research clause. A separate law cannot and should not be created for each and every research project which has a high level of public research interest on the basis of retrospective data and then possibly on a national level. This would cause fragmentation of legal regulations for research. In the case of particularly sensitive data on health, weighing up basic rights regarding determining what happens to personal data and the freedom of research can be different than where less critical data is concerned. However, there is no reason to preclude it completely and therefore to make one of the basic rights in fact absolute in certain cases.

#### *Section 2, a*

Art. 9, section 2, a specifies that data processing is legal if consent has been given. In contrast to the analogue principle in art. 6, section 1, a, the Commission's draft did not include tying consent to a specific purpose ("for one or more specific purposes"). Against the background of the more stringent protection here, this was inconsistent and was therefore amended in the current version. However, this version also constitutes an addition in comparison with the previous data-protection directive (see art. 8, paragraph 2, a). This clarification means that what is known as blanket consent, which to date was considered insufficient, is now to be ruled out all together at last. A specific purpose has to be specified on the consent form, with several specific purposes also possible. The critical factor is whether this wording and the way it is interpreted in the future precludes implementation of broad consent. This concept is a necessary condition for an in-depth evaluation of therapies, discovering risk factors or biomarkers at an early stage, recruitment support in new research projects and generating hypotheses. As a result, in terms of consent, the broad-consent concept is becoming more and more widespread in the case of consent for clinical basic research, especially where biobanks are concerned. On the one hand, when setting up

biobanks and databases it is not possible to foresee what actual research projects the samples and data will be used for and which research partners the samples and data will be sent to. On the other hand, during an actual research project, new research approaches can arise which can only be pursued by receiving further consent by the donors concerned if more stringent rules on specifying the purpose exist. To date, under German law, broad consent required for this type of research has not been excluded, particularly if the risks of long periods of storage are compensated for by appropriate technical and organisational measures, such as the TMF has proposed.

Even if a restrictive interpretation of the addendum “for one or more specific purposes” does not appear to be compulsory, there is much at risk because basic biomedical research in particular relies on more broad consent being possible. It would especially not be acceptable to demand a legal exception to the duty to obtain consent for important research projects that are in the public interest only because broad consent does not appear to be permissible.<sup>8</sup> The compromise negotiated with the Ethics Commissions in Germany regarding broad consent for biobank-based research shows that broad consent for a limited area, but which is in the interests of future research issues, is ethical acceptable. Furthermore, this showed that provisions can be found that allow both research and prevent the ethical risk of doing anything illegal. Therefore, appropriate clarification as part of this comprehensive legislative initiative would be urgently necessary which also reflects the current practice of obtaining ethics votes as additional, compensatory and trust-building measures.

After all, the recently passed regulation by the European Parliament and the Council on Clinical Trials on Medicinal Products for Human Use and on rescinding the 2001/20/EC directive in which there is an opening for declarations of consent in art. 28, section 2, are based on the previous development towards broad consent. Here the sponsor of a clinical trial is given the opportunity, as part of the procedure of seeking consent to participate in a clinical trial, of obtaining consent to further scientific research at the same time. Should broad consent now be excluded as part of the GDPR, researchers outside clinical trials would be put at an inappropriate disadvantage, or it would lead to inconsistencies requiring urgent clarification.

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<sup>8</sup> See Taupitz, J., The draft for a basic European data-protection regulation – risks for medical research. *Medizinrecht*, 2012. 30(7): Page 423-428.



### *Paragraph 2, h, i*

An exception to the prohibition on processing, also applies to data concerning health in h, if processing is required for health purposes. In this case, reference is made to the specifications and safeguards given in art. 81. The term “health purposes” seems fuzzy, for example healthcare research of the development of new therapies might or might not be included. It is not clear why the reference focuses on the term “health purposes” instead of going in detail into using data concerning health only for research purposes. It would make the Regulation clearer and easier to understand if all provisions that apply to data concerning health and the special protection it requires, were regulated in art. 81, particularly as the references to art. 81 on the one hand and art. 83 on the other do not always seem to be logical (see also art. 81 and 83).

In the case of medical research, if it is not to be interpreted as for a health purpose as specified in h, h allows processing of sensitive data under the general conditions of art. 83. In principle enabling the processing of sensitive data concerning health does appear to be understandable based on separate references. However, a problem is still the fuzzy term “health purposes” and the fact that in modern biomedical research a dividing line between research and healthcare, due to the way they are so closely related, is sometimes hard to determine. Similarly to German data-protection law (see article 13, section 2 and article 28, section 6 of the German Data-Protection Act) the previously criticised lack of a process of weighing up between research freedom and the right of individuals to determine what happens to their data would be only be compensated for here by the reference to art. 83 if art. 83 included an appropriate regulation. This is however not the case (see below).

### **Art. 17 – Right to be forgotten and erasure**

The Commission's draft does not just include the familiar obligations to delete data. Art. 17 states that in future there will also be a right to “be forgotten”. Included are also the obligations by third parties to delete the data they have been forwarded. This provision complies to a large extent with the TMFs current recommendations that have been discussed with data-protection bodies at a national level regarding passing on data and samples for research purposes.

It is not clear whether rendering personal data anonymous can replace deleting data. This alternative is vital for research purposes so that valuable sources of information are not lost.

### **Art. 33 – Data protection impact assessment**

In major and long-term biomedical research projects today, an impact assessment combined with a risk analysis is sometimes an integral part of the data-protection concept to be discussed with the data-protection officer or the supervisory authorities. Therefore, the proposed introduction of an impact assessment as specified in art. 33 of the Commission's draft is to be welcomed. According to paragraph 2, b an impact assessment would be compulsory for all research projects that use data concerning health, or according to d) when processing any genetic or biometric data. A reliable impact assessment and a risk analysis would be very costly, both in terms of drawing them up and analysing them. An unspecified demand for an impact assessment, which is not currently required under German law, would infringe the principle of proportionality. In the case of minor and short research projects where the data stays in the clinic giving the treatment, other provisions should apply regarding impact assessments than to cross-facility databases and biobanks which are comparatively long term and where the purposes of the data remains open-ended. Minor spin-offs (e.g. Kompetenznetz e.V.), which are encouraged in funding terms, are in particular usually not in a position to afford these sorts of measures because they lack manpower.

The TMF's generic data-protection concept for biobanks includes a detailed discussion on the risk parameters that apply when making differentiations.

#### *Regarding the Parliamentary draft*

The previous paragraph 2 was moved to a separate article, 32 a, which initially only establishes the unqualified necessity to carry out a risk assessment. Processing special types of personal data, as specified in article 9, paragraph 1 (which also includes data concerning health) and processing personal data in order to provide healthcare services, or for epidemiological trials, were mentioned as being special risks. In these cases, paragraph 3, c) indiscriminately states that an impact assessment is to be carried out as established in art. 33. As a result, this would apply to all processing steps regarding data concerning health and therefore all patient-driven biomedical research projects. Therefore, this version is no improvement on the original draft by the Commission. The problem of disproportionately high obstacles for smaller research projects remains.

### **Art. 34 – Prior authorisation and consultation**

In art. 34 the GDPR's draft stipulates a requirement for authorisation (paragraph 1) and consultation (paragraph 2). The controller is required to contact the supervisory body

responsible for authorisation (see art. 46 GDPR). Exceptions to this duty to obtain prior authorisation are not planned. Furthermore, no options to delegate by including internal or official data-protection officers are included, such as those allowed in the German data-protection law regarding reporting duties (see article 4d (2) German Data-Protection Act). As regards the duty to consult, a restriction is included that this only applies if the impact assessment in line with article 33 GDPR has not revealed any “concrete and high risks” (paragraph 2, a), or the supervisory authority considers consultation necessary regarding the processing steps stated in section 4 due to the nature, scope and/or purpose of the processing and the resulting and actual risks to the people affected (b). Under section 4, the supervisory authority must draw up a list of all processing steps that are subject to prior consultation under paragraph 2, b. Furthermore, these lists must be sent to the European Data-Protection Committee.

First of all, paragraphs 2 lit. b) and 4 make circular references to one another. Therefore, the reference in section 2, b) is redundant and should be dropped. More fundamental however is the problem that by its nature consultation has to be initiated by the body responsible and its data-protection officers, at least if consultation is to take place prior to authorisation. Therefore, the supervisory body is not yet aware that processing is upcoming. Therefore, from the point of view of the supervisory body, this criterion of necessity cannot be implemented in practice. The supervisory authority could at most define a catalogue of criteria, according to which the necessity of prior consultation could be established. The criterion stated in the GDPR regarding risks not stated in more detail is on the other hand much too vague to be a useful guideline.

All in all, the regulations suggested go way beyond the requirements of German data-protection law. The consequence would be that all private and public bodies would be flooded with consultations and authorisation procedures on all processing of personal data. If they process personal data, research projects would also be affected by this regulation and would have to allow for time-consuming procedures and delays, particularly since no deadlines have been specified for the authorisation procedures. The law governing doctors also includes a duty to be advised by the ethics commission concerned if personal data is processed (article 15 of the Professional Guidelines), so that in this case the duty of consultation by the supervisory authorities would create an occasionally redundant obstacle

to medical research.<sup>9</sup> Even if many research projects today seek discussion with the supervisory bodies concerned beforehand, an indiscriminate duty to obtain prior authorisation of all projects by the supervisory projects – particularly since no deadlines are given – is to be rejected.

#### *Regarding the Parliamentary draft*

Paragraph 1 has been dropped in the Parliamentary draft and this gets rid of the above-mentioned problem regarding impractical and disproportionately high levels of bureaucracy. The requirement in paragraph 2 to consult has remained and now states that consultation with the data-protection officer is required. Consultation with the supervisory authorities is compulsory in the above-mentioned cases only if a data-protection officer has not been appointed. For the most part this approximates the distribution of roles between local data-protection and supervisory authorities under German law. There is a change however regarding keeping procedural directories and the associated reporting duties. Both under the Commission's draft and in the current version, these must be kept by the supervisory authorities and not (as specified in German data-protection legislation) by the local data-protection officers.

Art. 34, section 2, b) also stipulates that the local data-protection officer can also make consultation necessary. We do believe this is an improvement, but does not solve the problem that consultation under data-protection law could be required at a much earlier stage in many research projects. In particular, projects funded by external sources must be considered where the applicants might need support in wording an application for funding, or an assessment of the consultation they might need during the course of a project. In this case, a catalogue of criteria would be more helpful than the fact that a data-protection officer or supervisory authority established the requirement.

#### **Art. 81 – Processing personal data concerning health**

Art. 9, paragraph 2, allows for an exception to the prohibition on processing sensitive data concerning health if the data is required for health purposes and it is subject to the specifications set out in art. 81. On the other hand, art. 81 section 1 states that processing personal data concerning health must be carried out in compliance with the provisions of this

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<sup>9</sup> see also Science Europe Position Statement, a.a.O. (Fn. 2), page 4.

Regulation and in particular with art. 9, paragraph 2, h. This reference to art. 9 appears to be circular. The comment that in addition to art. 9, section 2, h, the other provisions of the Regulation must be taken into account, makes the classification of art. 81 more difficult compared with the other provisions in the draft of the Regulation.

Furthermore, the system under articles 9, 81 and 83 is hard to understand even for readers who are practised at comprehending legal texts. While on the one hand art. 9, section 2, h, only allows processing of personal data concerning health in compliance with the provisions in art. 81 and merely for health-related purposes, art. 81, sections 1b, 1c and 2 also regulates the processing of medical data or health-related data for research purposes. However, for research purposes in section 2, i, the underlying art. 9 explicitly and exclusively refers to the provisions of art. 83. Therefore, these provisions would only be relevant if art. 83 referred to art. 81.

To what extent the provisions in section 1 apply to the requirements in special laws like the SGB [*German Social Security Code*], or law on physicians, is not the object of this comment, but would need to be looked into carefully.

#### *Regarding the Parliamentary draft*

New additions to the Parliamentary draft are paragraphs 1b, 1c and 2 which are relevant to research and paragraph 2 has had important additions made to it.

Art. 81, paragraph 1b regulates the processing of medical data solely for research purposes regarding issues of public health, insofar as consent is required for processing the data. In these cases, consent for one or several specific research projects that are similar to one another can be given. It also specifies that the person affected can revoke consent at any time. Initially it is not at all clear why in this case new terms such as “personal data concerning health” and “research for reasons of public interest” have been introduced without any clear reason as to what the meaning of these new terms is. Is medical data only considered data that is captured as part of treatment, but not in the strictest sense data concerning health? Does research for reasons of public interest in any way differ from health research otherwise? It is also unclear why in this case a restriction on consent is not just limited to one or several purposes, but one or several research projects that are similar to one another. As the paragraph concerned already places restrictions on research for health-related purposes, in this case only a specification regarding research on certain illnesses can be what is meant. However, this specification has attracted criticism from all sides. It is considered outdated because it seems artificial and hardly offers the person to whom the

data is related any extra protection. Therefore, a return to this practice would be a definite regression for research. The specification regarding fundamental revocability of consent appears redundant (see art. 7, paragraph 3).

Article 81, paragraph 1 c refers to the regulations of directive 2001/20/EC regarding consent to participation in scientific research in conjunction with clinical trials. This does appear in principle to be a good idea, although it is possibly redundant regarding other provisions that allow processing due to special statutory regulations (see art. 9, paragraph 2, g). In this case it should also be pointed out that the reference is ambiguous, and therefore confusing, because the directive quoted only refers to clinical testing as part of licensing procedures for pharmaceuticals and not to clinical trials in general. After all, a regulation on clinical testing with medicinal products for human use of 16 April 2014 does already exist that replaces this directive.

Under art. 81, paragraph 2, processing personal data concerning health is among other things permitted for scientific research purposes in line with the conditions and safeguards referred to in art. 83, but only if consent by the person in question is given. An exception to the requirement for consent is only possible based on the law of a Member State if the requirements of paragraph 2 a are fulfilled. However, the requirements regarding a legal exception to the rule by a Member State seem high: the research concerned must serve a purpose of superior public interest and it must be impossible to carry it out otherwise. The data must always be pseudonymised if no anonymisation is possible. Furthermore, the persons concerned must be able to object to processing at any time. In comparison with previous opportunities to carry out research with patient data in a hospital for internal purposes, based on some German laws on regional hospitals, the requirements seem to be too high and restrictive. The specification that data has to be anonymised is therefore misleading because anonymous data is no longer subject to the provisions of the Regulation. The option for people to object to processing is also a problem because it is not clear in what way the persons concerned have to be informed that their data is being processed. Without any information however, the option to object to processing will not effectively improve the legal position of the persons concerned.

The provision in art. 81, paragraph 2a misses out on the opportunity to make cross-border partnerships easier due to harmonisation at a European level based on standard regulations. These types of partnerships can be advisable and important even if the research data itself does not leave the facilities carrying out treatment. An example would be using data to

assess the feasibility of a trial, or to support recruiting in a hospital. Both these cases are currently modelled in the European EHR4CR project and the different statutory conditions are quite an obstacle.

However, as long as the fundamental requirement to obtain consent remains in place in paragraph 2, the option created in paragraph 2a regarding national legislation should be retained. This would also provide similar options for research using hospitals' own data, regardless of any consent, at least in some Member States and if applicable in line with previous regulations set out in regional hospital laws. Otherwise, retrospective usage of data is to a large extent precluded due to the requirement to obtain consent.

However, the obstacles in paragraph 2a are much higher than in the current directive (art. 8, paragraph 4). The requirement that it must be impossible to carry out the research in any other way is totally unrealistic in particular. Because in theory it will often be possible to carry it out in another way, for example by attempting to contact hundreds of data subjects at a later date in order to ask for their consent. In practice, this process could be so time-consuming that the research project in question would simply not take place. Therefore, we urgently suggest adding "with reasonable means" in order to allow research to be implemented in another way.

Furthermore, the last sentence in paragraph 2 a should be deleted. Because the right to opt out (if taken seriously) assumes that the data subjects have been informed of their rights as to the amount of time that it could take to obtain their consent.

We would also like to point out that in hospitals and sometimes in doctors' surgeries data concerning health is frequently processed to very high security standards and these should certainly not be slackened. With this in mind, it is advisable that research that takes place within a hospital or doctor's surgery and is therefore subject to the same standards of security, does not come up against additional obstacles. This is particularly the case since medical research (regardless of whether it focuses on healthcare research, therapy/pharmaceuticals, or basic research) in the final analysis always serves the patient who is the data subject at the same time.

### **Art. 83 – Processing for historical, statistical or scientific research purposes**

Basically we welcome the fact that the Commission's draft includes a standard governing research in the form of art. 83. Data-protection directive 95/46/EC did not include this type

of explicit provision. Furthermore, references are made to both processing general personal data in art. 6, paragraph 2 and data concerning health and a special category of personal data in art. 9, paragraph 2, in the context of research to art. 83.

However, particularly in the case of biomedical research and health research, the relationship between art. 83 and art. 81 remains unclear (see above art. 9, paragraph 2 h, as well as art. 81). As for sensitive and health data art. 9 applies as a more specific provision compared with art. 6, the principle of *lex specialis vis à vis* art. 81 and art. 83 appears to have been breached without it being clear which cases art. 81 (which is relevant to health data) applies to and which cases art. 83 (which is relevant to research in general) applies to. Because in paragraph 2 h, art. 9 already refers to art. 81 regarding data that is “necessary for health purposes”, while paragraph 2 i refers to research in art. 83. Then on the other hand, art. 81, paragraph 2 explicitly restricts research with data concerning health by requiring consent beforehand without the possibility of indicating the relationship of this restriction to health purposes.

Even if this question could be clarified via a teleological interpretation, these types of unhappy reference techniques are very damaging to research. Because legislative uncertainties are always time-consuming and require legal expertise which has a very negative impact on the research itself due to the associated costs and the time and manpower required, as well as the remaining risk. An aspect which should not be underestimated is also that in some circumstances very different interpretation could be developed regionally. This in turn would lead to fragmentation in the way the Regulation is dealt with, the very situation that the detailed provisions set out to avoid.

Therefore, we urgently suggest that all regulations regarding biomedical research be established in art. 81 which would then be the more specific regulation for the whole of this area. Art. 83 would then only be applied if art. 81 left scope for it.

Comments on individual aspects of art. 83 of the Commission's draft:

A noticeable aspect is the wording in section 1 that allows processing personal data for scientific research purposes only within the parameters of this Regulation.

Paragraph 1 establishes that priority is to be given to processing anonymised, or if required pseudonymised data, insofar as it can fulfil the research purpose. Noticeable in comparison with paragraph 2 is the fact that no condition is imposed for obtaining consent for processing the data. Paragraph 2 regulates the publication of personal data for the purposes stated and



alternatively requires a) consent in line with article 7 or b) an overarching interest of research vis à vis the interests and basic rights of the person concerned and c) publication by the persons concerned themselves. In paragraph 3, the Commission's draft also allows for a broad opening clause which would permit the Commission to pass secondary regulations for research.

#### *Paragraph 1*

It is unclear to what extent "for the purposes of this Regulation" means that the provisions in art. 83 are to be applied in addition to all other provisions in the Regulation. This would to some extent lead to opposing provisions, but cannot be completely excluded either due to the wording. At the very least, provisions that did not directly oppose each other would have to be considered parameters for research that also applied.

We fully support priority being given to anonymised or pseudonymised data. The TMF's generic data-protection concepts prove to what a wide extent research projects can be carried out based on pseudonymised data. It is worth pointing out that in contrast to the provisions in paragraph 2, there is no stipulation to obtain consent for processing data specified in paragraph 1. This allows widespread usage of data within facilities that have captured the data. Particularly as regards healthcare research and the retrospective secondary usage of clinical data, this is a vital condition for clarifying many issues. In Germany today, comparable regulations only exist under individual laws governing regional hospitals which do not exactly guarantee the standardisation aimed for here. This version is also not contradicted by the restrictive wording at the beginning of paragraph 1 that points out that the regulations in art. 1 only apply "within the limits of this Regulation". This is supported by the fact that in art. 6 and art. 9 the conditions specified in art. 83 are referred to as an alternative to consent as a legal basis in research.

#### *Paragraph 2*

We also agree with the regulations proposed in the Commission's draft regarding publication of personal data. We welcome the adoption of a "research clause" in paragraph 2, b) which weighs up the basic rights of research and the data subject's right to determine what happens to their own information. Similar regulations are included in the German Data Protection Act (see article 13, section 2 and article 28, section 6 German Data Protection Act).

As already discussed regarding art. 5 of the GDPR, we would like to point out that comparatively broad consent that does not go into every detail of the purposes concerned

must urgently be made possible and that for this purpose a clear and intelligible legal foundation needs to be established. In implementing their right to determining what happens to their information, test persons should be able to give consent to open-ended use of their data and samples for research purposes. The need for such a regulation will not become redundant by enabling research without consent because in cases where obtaining broad consent is possible, it should also be obtained. It is not an ethically justifiable solution to carry out research without obtaining consent only because the people affected are not allowed to sign a broad consent form.

### *Paragraph 3*

The consequences of the Commission's empowerment, defined in paragraph 3, cannot be foreseen at present. The scope of this provision is a problem for two reasons: on the one hand there is a lack of legitimation by Parliament and on the other the decrees are not restricted in any way under law. Therefore, this paragraph should be dropped.

### *Regarding the Parliamentary draft*

Only the first paragraph of the original art. 83 has remained in the current draft law passed by the European Parliament's plenary. The provisions in this paragraph now apply in accordance with the provisions of the Regulation and no longer within the restrictions of this Regulation. Therefore, we have to assume that provisions in other areas of the Regulation that do not directly contradict one another could also apply. Furthermore, processing pseudonymous data "to the highest technical standards" is a minimum and using personal data is no longer permissible. All measures need to be taken that prevent unauthorised conclusions as to the identity of the persons concerned. Recital 40, which clearly outlined that the usage of data for research purposes is reconcilable with the original reasons for capturing the data, has also been completely dropped.

As the regulations in paragraph 2 have been dropped, it can no longer be assumed on the other hand from the compulsory consent required there that an obligation for consent is lacking in paragraph 1. Furthermore, in art. 81, paragraph 2 now includes a requirement to obtain consent for processing data relating to health for research purposes in addition to the conditions in art. 83. As a result, we can assume that no biomedical research projects involving personal data can be carried out any more. Important research projects that can only be carried out by using large databases retrospectively and for which no subsequent consent can be obtained would be prevented in this way. The original purpose of art. 83, to carry out research with personal data where consent cannot be obtained, or which is very

complicated to obtain, but where special care is taken with this data, has therefore not been achieved. What remains is art. 83, which does not foster research, but in comparison with other, purely commercial usage of data actually puts research at a disadvantage. The reason is that the article does not just maintain the general requirement to obtain consent, but also specifies the absolute requirement to pseudonymisation of data, if anonymisation of data is not specified. This restriction should be viewed as going further than the general rules on data economy (see art. 5, c). Research with individual patients whose data cannot be effectively pseudonymised, would no longer be possible even when consent is provided. In this case, during the negotiation process the condition for a basic right for science to be given a privilege has changed into a disproportionate restriction placed on the world of science. Because on the one hand, the stringent obligation placed on the scientific world to give priority to anonymising and pseudonymising data is a tool for creating practical concordance regarding basic rights which respects data-protection issues and at the same time justifies facilitating scientific projects. On the other hand, it justifies making the implementation of scientific projects easier by treating pseudonymisation and anonymisation of data under law equally, or by facilitating the organisation of pseudonymisation of data (see for example article 28, section 1 of the Data Protection Act of North-Rhine Westphalia). This privilege of pseudonymisation is necessary with regard to the implementation of fundamental rights.

Publishing medical data is also a problem because particularly in the case of rare diseases no safe anonymisation of data can be provided, is no longer regulated or cannot be carried out based on consent if the data cannot be rendered pseudonymous at the very least.

We have already gone into the problems of empowerment of the Commission outlined in paragraph 3. Therefore, we agree to the proposal to delete this paragraph.