

## CONTACT

Dr Beth Thompson, Policy Adviser  
+44 (0) 20 7611 7303 / [b.thompson@wellcome.ac.uk](mailto:b.thompson@wellcome.ac.uk)  
[wellcome.ac.uk/dataprotectionregulation](http://wellcome.ac.uk/dataprotectionregulation)

## Academic research perspective on the European Commission, Parliament and Council texts of the proposal for a General Data Protection Regulation - 2012/0011(COD)

### INDEX

Issue	Relevant chapter, articles and recitals	Priority	Page
Definition of personal data/data subject and regulation of pseudonymous data	Chapter I: Article 4(2) and new text on pseudonymisation	<b>* high</b>	2
Other definitions	Chapter I: Article 4(10) and (12)		3
Principles of data protection: further processing and storage	Chapter II: Article 5(b) and Recital 40; Article 5(e)	<b>* high</b>	4
Lawfulness of processing	Chapter II: Article 6(2)	<b>* high</b>	6
Conditions for consent	Chapter II: Recital 25aa (from Council text)	<b>* high</b>	6
Processing of special categories of personal data	Chapter II: Article 9(2)i		7
Data subject rights	Chapter III: Article 14; Article 17; Article 19		8
International transfers	Chapter V: Article 42		9
Freedom of expression	Chapter IX: Article 80		10
Data concerning health	Chapter IX: Article 81	<b>** critical</b>	11
Processing for historical, statistical and scientific research purposes	Chapter IX: Article 83	<b>** critical</b>	12

### KEY

Text **added** by the Parliament/Council is in ***bold italics***

Text **deleted** by the Parliament/Council is ~~struck through~~ or indicated by (...)

### OTHER DOCUMENTS

[Joint statement from over 90 patient, academic and non-commercial research organisations summarising our position on the three texts](#)

	Commission proposal January 2012	European Parliament March 2014	Council of Ministers text June 2015	Analysis and proposed solution
<b>Definition of personal data/data subject and regulation of pseudonymous data – * high priority</b>				
<b>Article 4</b>	<p>(1) 'data subject' means an identified natural person or a natural person who can be identified, directly or indirectly, <b>by means reasonably likely to be used</b> by the controller or by any other natural or legal person, in particular by reference to an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person;</p> <p>(2) 'personal data' means any information relating to a data subject;</p>	<p>(1) '<del>data subject</del>' means an identified natural person or a natural person who can be identified, directly or indirectly, <del>by means reasonably likely to be used</del> by the controller or by any other natural or legal person, in particular by reference to an identification number, location data, online identifier or to one or more factors specific to the <del>physical, physiological, genetic, mental, economic, cultural or social identity</del> of that person;</p> <p>(2) 'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, unique identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social or gender identity of that person;</p>	<p>(1) '<b>personal data</b>' means any <b>information relating to an identified or identifiable natural person ('data subject');</b> an identifiable person is one who can be identified, directly or indirectly by means reasonably likely to be used by the controller or by any other natural or legal person, in particular by reference to <b>an identifier such as a name</b>, an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person.</p> <p>(2) (...)</p>	<p><b>Restore “means reasonably likely” test from Commission proposal</b> (highlighted for emphasis) <b>in the definition of “personal data” or “data subject”</b>.</p> <p>This will ensure consistency with Recital 23 and continue the approach of the Data Protection Directive, which enables an element of proportionality in determining whether data can lead to the identification of an individual. This is particularly important in research, where pseudonymised data are often used in a very robust system with strict organisational, legal and technological safeguards to protect privacy.</p>

Article 4 cont.		<i>(2a) 'pseudonymous data' means personal data that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution;</i>	<i>(3b) 'pseudonymisation' means the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution to an identified or identifiable person</i>	<p><b>Support the Commission's approach of not including a definition on pseudonymous data or pseudonymisation</b>, which works well under the Data Protection Directive since it has enabled a proportionate approach to interpreting the scope of the legislation.</p> <p>If a definition is to be included, the <b>Council's definition is preferred to Parliament's</b> from the research perspective.</p> <p>Council's definition of the process defines one approach to ensure the security of personal data, rather than creating a new and inflexible category of personal data.</p>
<b>Other definitions</b>				
Article 4(10)	'genetic data' means all data, of whatever type, concerning the characteristics of an individual which are inherited or acquired during early prenatal development;	'genetic data' means all <b>personal</b> data <b>relating</b> to the <b>genetic</b> characteristics of an individual which <b>have been</b> inherited or acquired <b>as they result from an analysis of a biological sample from the individual in question, in particular by chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis or analysis of any other element enabling equivalent information to be obtained;</b>	'genetic data' means all <b>personal</b> data <b>relating to the genetic</b> characteristics of an individual <b>that have been inherited or acquired, (...) which give unique information about the physiology or the health of that individual, resulting in particular from an analysis of a biological sample from the individual in question;</b>	<b>Support the Parliament or Council text</b> , which clarify that the definition is restricted to personal data.
Article 4(12)	'data concerning health' means any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual;	'data concerning health' means any <b>personal data</b> which relates to the physical or mental health of an individual, or to the provision of health services to the individual;	'data concerning health' means <b>data related</b> to the physical or mental health of an individual, <b>which reveal information about his or her health status;</b>	<b>Support the inclusion of "personal data" from the Parliament's text</b> , which clarifies that the definition is restricted to personal data.

**Principles of data protection: further processing and storage – \* high priority**

<p><b>Article 5(b)</b></p>	<p>Personal data must be: (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes;</p>	<p>Personal data (...) <b>shall</b> be: (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes <b>(purpose limitation);</b></p>	<p>Personal data must be (b) collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes; <b>further processing of personal data for archiving purposes in the public interest or scientific, statistical or historical purposes shall in accordance with Article 83 not be considered incompatible with the initial purposes;</b></p>	<p><b>Support the Council text</b>, which provides greatest clarity that scientific research, statistical or historical purposes can be considered “not incompatible” purposes in terms of further processing, consistent with the Data Protection Directive Article 6(1)(b).</p> <p>This concept is included in Recital 40 of the Commission’s text, but is clearer in the Council text. However, the concept of further processing and “not incompatible purposes” is removed completely from the Parliament’s text.</p> <p>Facilitating further processing of data for research is important as it enables routinely collected data – for example hospital records – to be used in studies.</p> <p>See also Recital 40.</p>
<p><b>Recital 40</b></p>	<p>The processing of personal data for other purposes should be only allowed where the processing is compatible with those purposes for which the data have been initially collected, in particular where the processing is necessary for historical, statistical or scientific research purposes. Where the other purpose is not compatible with the initial one for which the data are collected, the controller should obtain the consent of the data subject for</p>	<p><del>The processing of personal data for other purposes should be only allowed where the processing is compatible with those purposes for which the data have been initially collected, in particular where the processing is necessary for historical, statistical or scientific research purposes. Where the other purpose is not compatible with the initial one for which the data are collected, the controller should obtain the consent of the data subject for</del></p>	<p>The processing of personal data for other purposes <b>than the purposes for which the data have been initially collected</b> should be only allowed where the processing is <b>compatible</b> with those purposes for which the data have been initially collected. <b>In such case no separate legal basis is required other than the one which allowed the collection of the data. (...) If the processing is necessary for the performance of a task carried out in the public interest or in</b></p>	<p><b>Support Commission and Council texts</b>, which maintain the concept of further processing. This concept is removed in the Parliament’s text.</p> <p>Facilitating further processing of data for research is important as it enables routinely collected data – for example hospital records – to be used in studies.</p> <p>See also Article 5(b).</p>

	<p>this other purpose or should base the processing on another legitimate ground for lawful processing, in particular where provided by Union law or the law of the Member State to which the controller is subject. In any case, the application of the principles set out by this Regulation and in particular the information of the data subject on those other purposes should be ensured.</p>	<p><del>this other purpose or should base the processing on another legitimate ground for lawful processing, in particular where provided by Union law or the law of the Member State to which the controller is subject. In any case, the application of the principles set out by this Regulation and in particular the information of the data subject on those other purposes should be ensured.</del></p>	<p><b><i>the exercise of official authority vested in the controller, Union law or Member State law may determine and specify the tasks and purposes for which the further processing shall be regarded as lawful. The further processing (...) for archiving purposes in the public interest or, statistical, scientific or historical (...) purposes (...) or in view of future dispute resolution should be considered as compatible lawful processing operations.</i></b> etc.</p>	
<p><b>Article 5(e)</b></p>	<p>(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the data will be processed solely for historical, statistical or scientific research purposes in accordance with the rules and conditions of Article 83 and if a periodic review is carried out to assess the necessity to continue the storage;</p>	<p>(e) kept in a form which permits <b><i>direct or indirect</i></b> identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the data will be processed solely for historical, statistical or scientific research <b><i>or for archive</i></b> purposes in accordance with the rules and conditions of Articles 83 <b><i>and 83a</i></b> and if a periodic review is carried out to assess the necessity to continue the storage, <b><i>and if appropriate technical and organisational measures are put in place to limit access to the data only for these purposes (storage minimisation);</i></b></p>	<p>(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed (...); <b><i>personal data may be stored for longer periods insofar as the data will be processed for archiving purposes in the public interest or scientific, statistical, or historical purposes in accordance with Article 83 subject to implementation of the appropriate technical and organisational measures required by the Regulation in order to safeguard the rights and freedoms of data subject;</i></b></p>	<p><b>Support the inclusion of this derogation from limits on data storage for research, which is included in all three texts.</b></p> <p>The Council's text provides greater legal certainty than Parliament's on the technical and organisational measures that would be needed to benefit from the derogation.</p> <p>The requirement for periodic review in the Commission and Parliament texts is acceptable.</p>

**Lawfulness of processing – \* high priority**

<p><b>Article 6(2)</b></p>	<p>Processing of personal data which is necessary for the purposes of historical, statistical or scientific research shall be lawful subject to the conditions and safeguards referred to in Article 83.</p>	<p>Processing of personal data which is necessary for the purposes of historical, statistical or scientific research shall be lawful subject to the conditions and safeguards referred to in Article 83.</p>	<p>Processing of personal data which is necessary for <b>archiving purposes in the public interest, or for</b> historical, statistical or scientific purposes shall be lawful subject <b>also</b> to the conditions and safeguards referred to in Article 83.</p>	<p><b>Support the Commission and Parliament’s texts</b> as these provide a legal basis for historical, statistical or scientific research, independent of Article 6(1), provided the conditions of Article 83 are met. This would provide valuable legal certainty for the processing of personal data for research.</p> <p>The inclusion of “also” in the Council’s text creates legal uncertainty in how Article 6(2) relates to Article 6(1) and appears to impose additional requirements to legitimise processing for research compared to all other sectors.</p> <p>If Article 6(2) is not maintained, it is important to provide clarity that legitimate interests can be used as a legal basis for research as an alternative to consent, to provide greater consistency in interpretation across the EU.</p>
----------------------------	--	--	---	---

**Conditions for Consent – \* high priority**

<p><b>Recital 25aa</b></p>		<p>Note: Compare concept of “consent for specific and similar purposes” in Article 81(1b) (see page 11)</p>	<p><b><i>It is often not possible to fully identify the purpose of data processing for scientific purposes at the time of data collection. Therefore data subjects can give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas</i></b></p>	<p><b>Support amendment from Council</b> as this enables some flexibility in the interpretation of the definition of consent in the context of scientific research, which better reflects current practice in research in many Member States. This also seems consistent with Parliament’s intention in Article 81.</p> <p>Proposal to amend the Council’s text to address the lack of clarity</p>
----------------------------	--	---	--	--

			<p><b>of research or parts of research projects to the extent allowed by the intended purpose and provided that this does not involve disproportionate efforts in view of the protective purpose.</b></p>	<p>in the final sentence:</p> <p>It is often not possible to fully identify the purpose of data processing for scientific purposes at the time of data collection. Therefore data subjects can give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. <b>As far as possible</b>, data subjects should have the opportunity to give their consent <b>for the use of their personal data in further scientific research independently of the immediate research purpose.</b> <del>only to certain areas of research or parts of research projects to the extent allowed by the intended purpose and provided that this does not involve disproportionate efforts in view of the protective purpose.</del></p>
--	--	--	---	--

**Processing of special categories of personal data**

<p><b>Article 9(2)(i)</b></p>	<p>1. The processing of personal data, revealing race or ethnic origin, political opinions, religion or beliefs, trade-union membership, and the processing of genetic data or data concerning health or sex life or criminal convictions or related security measures shall be prohibited.</p> <p>2. Paragraph 1 shall not apply where:</p> <p>(i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards</p>	<p>1. The processing of personal data, revealing race or ethnic origin, political opinions, religion or <b>philosophical beliefs, sexual orientation or gender identity, trade-union membership and activities</b>, and the processing of genetic <b>or biometric</b> data or data concerning health or sex life, <b>administrative sanctions, judgments,</b> criminal <b>or suspected offences</b>, convictions or related security measures shall be prohibited.</p> <p>2. Paragraph 1 shall not apply <del>where</del> <b>if one of the following applies:</b></p>	<p>1. The processing of personal data, revealing <b>racial</b> or ethnic origin, political opinions, religious or <b>philosophical</b> beliefs, trade-union membership, and the processing of genetic data or data concerning health or sex life (...) shall be prohibited.</p> <p>2. Paragraph 1 shall not apply if one of the following applies (...)</p> <p>(i) processing is necessary for <b>archiving purposes in the public interest or</b> historical, statistical or scientific (...) purposes <b>and</b> subject to the conditions and safeguards <b>laid</b></p>	<p><b>Support Commission and Parliament texts</b> of Article 9(2)(i), which are clearer than the Council's approach.</p> <p>Safeguards are already described in Article 83 so the reference to "conditions and safeguards laid down in Union or Member State law, including those referred to in Article 83" in the Council text is duplicative and creates ambiguity.</p> <p>Any additional safeguards for the processing of different types of data in scientific research should be provided for in Article 83 to</p>
-------------------------------	--	---	---	--

	referred to in Article 83; or	(i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83; or	<b>down in Union or Member State law, including those referred to in Article 83.</b>  <b>5. Member States may maintain or introduce more specific provisions with regard to genetic data or health data. This includes the possibility for Member States to introduce further conditions for the processing of these data.</b>	ensure clarity.
<b>Data subject rights</b>				
<b>Article 14(5)</b> Information to the data subject	Paragraphs 1 to 4 shall not apply, where: ... (b) the data are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort; or	Paragraphs 1 to 4 shall not apply, where: ... (b) the data <b>are processed for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Articles 81 and 83</b> , are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort <b>and the controller has published the information for anyone to retrieve</b> ; or	Paragraphs 1 to 3a shall not apply where and insofar as: ... (b) the provision of such information (...) proves impossible or would involve a disproportionate effort; <b>in such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests</b> ; or	<b>Support the inclusion of this derogation from information to the data subject, which is included in all three texts.</b>  It is important to ensure consistency with any derogations from data subject rights listed in Article 83.
<b>Article 17(3)</b> Right to be forgotten and to erasure	The controller shall carry out the erasure without delay, except to the extent that the retention of the personal data is necessary: ... (b) for reasons of public interest in the area of public health in accordance with Article 81; (c) for historical, statistical and scientific research purposes in accordance with Article 83;	The controller <b>and, where applicable, the third party</b> shall carry out the erasure without delay, except to the extent that the retention of the personal data is necessary: ... (b) for reasons of public interest in the area of public health in accordance with Article 81; (c) for historical, statistical and scientific research purposes in accordance with Article 83;	<b>Paragraphs 1, 1a and 2a shall not apply</b> to the extent that (...) <b>processing</b> of the personal data is necessary: ... (c) for reasons of public interest in the area of public health in accordance with Article <b>9(2) (h) and (hb) as well as Article 9(4)</b> ; (d) for <b>archiving purposes in the public interest or for scientific, statistical and historical</b> (...) purposes in accordance with <b>Article 83</b> ;	<b>Support the inclusion of this derogation from the right to be forgotten and to erasure, which is included in all three texts.</b>  It is important to ensure consistency with any derogations from data subject rights listed in Article 83.



<p><b>Article 19</b> Right to object</p>	<p>1. The data subject shall have the right to object, on grounds relating to their particular situation, at any time to the processing of personal data which is based on points (d), (e) and (f) of Article 6(1), unless the controller demonstrates compelling legitimate grounds for the processing which override the interests or fundamental rights and freedoms of the data subject.</p>	<p>1. The data subject shall have the right to object at any time to the processing of personal data which is based on points (d) <b>and</b> (e) of Article 6(1), unless the controller demonstrates compelling legitimate grounds for the processing which override the interests or fundamental rights and freedoms of the data subject.</p> <p>2. Where <b>the processing of personal data is based on point (f) of Article 6(1)</b>, the data subject shall have <b>at any time and without any further justification</b>, the right to object free of charge <b>in general or for any particular purpose</b> to the processing of their personal data.</p>	<p><b>2aa. Where personal data are processed for historical, statistical or scientific purposes the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data concerning him or her, unless the processing is necessary for the performance of a task carried out for reasons of public interest.</b></p>	<p><b>Support Council text</b> to ensure a right to object for data subjects where their personal data are processed for historical, statistical or scientific purposes, coupled with a clear derogation restricted to where this processing is necessary for reasons of public interest.</p> <p>While data subjects should be able to exert this right as far as possible, it is also important to maintain a public interest derogation, for example to permit important research across a complete sample in an epidemic.</p> <p>It is important to ensure consistency with any derogations from data subject rights listed in Article 83.</p>
<p><b>International transfers</b></p>				
<p><b>Article 42</b></p>	<p>(5) Where the appropriate safeguards with respect to the protection of personal data are not provided for in a legally binding instrument, the controller or processor shall obtain prior authorisation for the transfer, or a set of transfers, or for provisions to be inserted into administrative arrangements providing the basis for such transfer. Such authorisation by the supervisory authority shall be in accordance with point (a) of Article 34(1). If the transfer is related to processing activities which concern data subjects in another Member State or other Member States, or substantially affect the free movement of personal data</p>	<p><del>(5) Where the appropriate safeguards with respect to the protection of personal data are not provided for in a legally binding instrument, the controller or processor shall obtain prior authorisation for the transfer, or a set of transfers, or for provisions to be inserted into administrative arrangements providing the basis for such transfer. Such authorisation by the supervisory authority shall be in accordance with point (a) of Article 34(1). If the transfer is related to processing activities which concern data subjects in another Member State or other Member States, or substantially affect the free movement of personal data</del></p>	<p><b>2a Subject to the authorisation from the competent supervisory authority, the appropriate safeguards referred to in paragraph 1 may also be provided for, in particular, by:</b> <b>(a)</b> contractual clauses between the controller or processor and the <b>controller, processor or the recipient of the data (...)</b> <b>in the third country or international organisation;</b> or</p>	<p><b>Support Commission and Council texts</b>, which would enable international transfers to be based on prior authorisation by the supervisory authority as an alternative to other routes such as legally binding instruments.</p> <p>International research collaborations are an important component of academic and commercial scientific research and may require international transfers of personal data. Removing the option to seek prior authorisation as a basis for international transfers may compromise the ability to transfer data countries outside the EU that collaborate in research.</p>

	within the Union, the supervisory authority shall apply the consistency mechanism referred to in Article 57.	<del>within the Union, the supervisory authority shall apply the consistency mechanism referred to in Article 57.</del>		
<b>Freedom of expression</b>				
<b>Article 80</b>	<p>1. Member States shall provide for exemptions or derogations from the provisions on the general principles in Chapter II, the rights of the data subject in Chapter III, on controller and processor in Chapter IV, on the transfer of personal data to third countries and international organisations in Chapter V, the independent supervisory authorities in Chapter VI and on co-operation and consistency in Chapter VII for the processing of personal data carried out solely for journalistic purposes or the purpose of artistic or literary expression in order to reconcile the right to the protection of personal data with the rules governing freedom of expression.</p> <p>2. Each Member State shall notify to the Commission those provisions of its law which it has adopted pursuant to paragraph 1 by the date specified in Article 91(2) at the latest and, without delay, any subsequent amendment law or amendment affecting them.</p>	<p>1. Member States shall provide for exemptions or derogations from the provisions on the general principles in Chapter II, the rights of the data subject in Chapter III, on controller and processor in Chapter IV, on the transfer of personal data to third countries and international organisations in Chapter V, the independent supervisory authorities in Chapter VI, on co-operation and consistency in Chapter VII <b>and specific data processing situations in Chapter IX whenever this is necessary</b> in order to reconcile the right to the protection of personal data with the rules governing freedom of expression <b>in accordance with the Charter of Fundamental Rights of the European Union.</b></p>	<p>1. <b><i>The national law of the Member State shall (...) reconcile the right to the protection of personal data pursuant to this Regulation with the right to freedom of expression and information, including the processing of personal data for journalistic purposes and the purposes of academic, artistic or literary expression.</i></b></p> <p>2. <b><i>For the processing of personal data carried out for journalistic purposes or the purpose of academic artistic or literary expression, Member States shall provide for exemptions or derogations from the provisions in Chapter II (principles), Chapter III (rights of the data subject), Chapter IV (controller and processor), Chapter V (transfer of personal data to third countries or international organizations), Chapter VI (independent supervisory authorities), Chapter VII (co-operation and consistency) if they are necessary to reconcile the right to the protection of personal data with the freedom of expression and information (...).</i></b></p>	<p><b>Support Council text</b>, which would clearly enable Member States to provide derogations for academic expression, which was not included in the Commission proposal. The Parliament text does create scope for such derogations but is less clear since it does not include the word “academic”.</p> <p>It is important that arts and humanities research should benefit from derogations because research in areas such as politics and history is unlikely to be compatible with the research model set out in Article 83 and may not be permitted otherwise.</p>

**Data concerning health – critical priority \*\***

<p><b>Article 81</b></p>	<p>2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies, is subject to the conditions and safeguards referred to in Article 83</p>	<p><b>1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time.</b></p> <p><b>1c. For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC of the European Parliament and of the Council<sup>1</sup> shall apply.</b></p> <p>2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies, is <b>shall be permitted only with the consent of the data subject, and shall be</b> subject to the conditions and safeguards referred to in Article 83.</p> <p><b>2a. Member States law may provide for exceptions to the requirement of consent for</b></p>	<p>(...)</p> <p>[Note that much of the original content of the Commission's draft has been moved to Article 9(2)(h) and (hb) and Article 9(4), not deleted.]</p>	<p><b>Support Commission text of Article 81(2)</b>, which would provide clarity that processing of data concerning health for historical, statistical or scientific research purposes is covered by Article 83, not Article 81. The Council and Parliament texts do not provide this clarity.</p> <p>The Parliament text on Article 81 would have severe unintended consequences by restricting and preventing vital research studies. A more detailed analysis is available <a href="#">here</a>.<sup>1</sup> <b>We appreciate Parliament's concern that the Commission's proposal does not adequately reflect the importance of strict safeguards for the use of data concerning health in research without consent. We propose that provisions for stronger safeguards compared to the Commission text for this type of processing could be included in Article 83 (see below).</b></p>
--------------------------	--	---	--	--

<sup>1</sup> [wellcome.ac.uk/dataprotectionregulation](http://wellcome.ac.uk/dataprotectionregulation)

		<p><i>research, as referred to in paragraph 2, with regard to research that serves a high public interest, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent unwarranted re-identification of the data subjects. However, the data subject shall have the right to object at any time in accordance with Article 19.</i></p>		
--	--	---	--	--

**Processing for historical, statistical and scientific research purposes – critical priority \*\***

<p><b>Article 83</b></p>	<p>1. Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:</p> <p>(a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;</p> <p>(b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner.</p> <p>2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly</p>	<p>1. Within the limits of <i>In accordance with the rules set out in</i> this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:</p> <p>(a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;</p> <p>(b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information as long as these purposes can be fulfilled in this manner. <b><i>under the highest technical standards, and all necessary measures are taken to prevent unwarranted re-</i></b></p>	<p><b><i>1. Where personal data are processed for scientific, statistical or historical purposes Union or Member State law may, subject to appropriate safeguards for the rights and freedoms of the data subject, provide for derogations from Articles 14a(1) and (2), 15, 16, 17, 17a, 17b, 18 and 19, insofar as such derogation is necessary for the fulfilment of the specific purposes.</i></b></p> <p><b><i>1a. Where personal data are processed for archiving purposes in the public interest, Union or Member State law may, subject to appropriate safeguards for the rights and freedoms of the data subject, provide for derogations from</i></b></p>	<p><b>Support Council text, or a compromise solution that permits the breadth of the exemptions in the Commission and Council text, but introduces further, proportionate safeguards to ensure personal data are used safely and securely in research and prevent misuse of the research exemptions.</b></p> <p>We appreciate Parliament's concern that further safeguards are needed where data concerning health are to be processed in research without consent. <b>We propose that Member States should be able to provide for additional suitable and specific safeguards to reconcile the right to the protection of data</b></p>
--------------------------	---	--	---	---

	<p>disclose personal data only if:</p> <p>(a) the data subject has given consent, subject to the conditions laid down in Article 7;</p> <p>(b) the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or</p> <p>(c) the data subject has made the data public.</p> <p>3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.</p>	<p><b>identification of data subjects.</b></p> <p><del>2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if:</del></p> <p><del>(a) the data subject has given consent, subject to the conditions laid down in Article 7;</del></p> <p><del>(b) the publication of personal data is necessary to present research findings or to facilitate research insofar as the interests or the fundamental rights or freedoms of the data subject do not override these interests; or</del></p> <p><del>(c) the data subject has made the data public.</del></p> <p><del>3. The Commission shall be empowered to adopt delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the processing of personal data for the purposes referred to in paragraph 1 and 2 as well as any necessary limitations on the rights of information to and access by the data subject and detailing the conditions and safeguards for the rights of the data subject under these circumstances.</del></p>	<p><b>Articles 14a(1) and (2), 15, 16, 17, 17a, 17b, 18, 19, 23, 32, 33 and 53 (1b)(d) and (e), insofar as such derogation is necessary for the fulfilment of these purposes.</b></p> <p><b>1b. In case a type of processing referred to in paragraphs 1 and 1a serves at the same time another purpose, the derogations allowed for apply only to the processing for the purposes referred to in those paragraphs.</b></p> <p><b>2. The appropriate safeguards referred to in paragraphs 1 and 1a shall be laid down in Union or Member State law and be such to ensure that technological and/or organisational protection measures pursuant to this Regulation are applied to the personal data (...), to minimise the processing of personal data in pursuance of the proportionality and necessity principles, such as pseudonymising the data, unless those measures prevent achieving the purpose of the processing and such purpose cannot be otherwise fulfilled within reasonable means.</b></p> <p>3. (...).</p>	<p><b>with the processing of data concerning health for scientific research purposes under point (i) of Article 9(2).</b></p> <p>Although harmonisation to appropriate standards would strengthen the research environment in the EU, <b>we recognise the need for flexibility to allow Member States to implement culturally and socially acceptable derogations and safeguards.</b></p> <p><b>We would be happy to discuss our proposal for a compromise amendment on request.</b></p>
--	--	--	---	--