Statement by the German Data Forum on the Current Drafts of the EU General Data Protection Regulation (EU-GDPR)

SAFEGUARDING INNOVATIVE RESEARCH IN THE SOCIAL AND ECONOMIC SCIENCES

Evaluation of research-relevant sections in the proposed EU General Data Protection Regulation
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Evaluation of research-relevant sections in the proposed EU General Data Protection Regulation

August 5, 2015

The aim of this statement by the German Data Forum is to positively influence and support the triilogue negotiations (EP, EU Commission, Council) and to voice the needs of social and economic research.

The German Data Forum offers a synopsis of the regulation’s research relevant sections. This statement prioritizes the existing drafts by the European institutions, currently under negotiation in the triilogue, from the viewpoint of the social and economic sciences. The aim is to respond directly to the current state of negotiations and to support those specific draft proposals that impose the least burden on empirical research.

At this point, the German Data Forum chooses not to issue general recommendations and fundamental remarks. We refer to the statement of 24.02.2015¹ and the joint statement on the EU-GDPR of the Alliance of Science Organizations in Germany.²

The German Data Forum stresses the need for securing a uniform application of the EU-GDPR across the common European research area. This is all the more important as rules for implementation through delegated acts (with or without parliamentary scrutiny) have not been included in the drafts of the EU Parliament and Council and as it remains uncertain whether national reservations to regulations will be included in the final EU-GDPR.

The German Data Forum emphasizes that it is important and necessary to involve science in an extensive manner by setting up a “Scientific Advisory Board” as part of the Data Protection Commission stipulated in the EU-GDPR. This is the best way of developing and implementing common codes of conduct and other standards through a common discourse in the European research area. The German Data Forum appeals to all institutions involved in supporting the triologue and also to the German Federal Government to support this proposal.

¹ http://www.ratswd.de/dl/Statement_GDPR-German_Data_Forum.pdf
(23) The principles of data protection should apply to any information concerning an identified or identifiable natural person. To determine whether a person is identifiable, account should be taken of all the means reasonably likely to be used either by the controller or by any other person to identify or single out the individual directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the individual, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration both available technology at the time of the processing and technological development. The principles of data protection should therefore not apply to anonymous data, which is information that does not relate to an identified or identifiable natural person. This Regulation does therefore not concern the processing of such anonymous data, including for statistical and research purposes.

(23b) In order to create incentives for applying pseudonymisation when processing personal data, measures of pseudonymisation whilst allowing general analysis should be possible within the same controller when the controller has taken technical and organisational measures necessary to ensure that the provisions of this Regulation are imple-

<table>
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Recital 23

(23) The principles of data protection should apply to any information concerning an identified or identifiable person. To determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the individual. The principles of data protection should not apply to data rendered anonymous in such a way that the data subject is no longer identifiable.
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Recital 25

Consent should be given explicitly by any appropriate method enabling a freely given specific and informed indication of the data subject’s wishes, either by a statement or by a clear affirmative action by the data subject, ensuring that individuals are aware that they give their consent to the processing of personal data, including by ticking a box when visiting an Internet website or by any other statement or conduct which clearly indicates in this context the data subject’s acceptance of the proposed processing of their personal data. Silence or inactivity should therefore not constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. If the data subject’s consent is to be given following an electronic request, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.

Consent should be given explicitly by any appropriate method enabling a freely given specific and informed indication of the data subject’s wishes, either by a statement or by a clear affirmative action that is the result of choice by the data subject, ensuring that individuals are aware that they give their consent to the processing of personal data. Clear affirmative action could include ticking a box when visiting an Internet website or any other statement or conduct which clearly indicates in this context the data subject’s acceptance of the proposed processing of their personal data. Silence, mere use of a service or inactivity should therefore not constitute consent. Consent should cover all processing activities carried out for the same purpose or purposes. If the data subject’s consent is to be given following an electronic request, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.

Consent should be given unambiguously by any appropriate method enabling a freely given specific and informed indication of the data subject’s wishes, either by a written, including electronic, oral statement or, if required by specific circumstances, by any other clear affirmative action by the data subject signifying his or her agreement to personal data relating to him or her being processed. This could include ticking a box when visiting an Internet website or any other statement or conduct which clearly indicates in this context the data subject’s acceptance of the proposed processing of their personal data. Silence or inactivity should therefore not constitute consent. Where it is technically feasible and effective, the data subject’s consent to processing may be given by using the appropriate settings of a browser or other application. In such cases it is sufficient that the data subject receives the information needed to give freely specific and informed consent when starting to use the service. (…). Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, unambiguous consent should be granted for all of the processing purposes. If the data subject’s consent is to be given following an electronic request, the request must be clear, concise and not unnecessarily disruptive to the use of the service for which it is provided.

(25a) Genetic data should be defined as personal data relating to the genetic characteristics of an individual which have been inherited or acquired as they result from an analysis of a biological sample from the individual 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.
|-------------------------------------------------------------|-------------------------------------------------|----------------------------------------|-------------------------------------|

(31) In order for processing to be lawful, personal data should be processed on the basis of the consent of the person concerned or some other legitimate basis, laid down by law, either in this Regulation or in other Union or Member State law as referred to in this Regulation.

(31a) Wherever this Regulation refers to a legal basis or a legislative measure, this does not necessarily require a legislative act adopted by a parliament, without prejudice to requirements pursuant the constitutional order of the Member State concerned, however such legal basis or legislative measure should be clear and precise and its application foreseeable for those subject to it as required by the case law of the Court of Justice of the European Union and the European Court on Human Rights.

Recital 31

(31) In order for processing to be lawful, personal data should be processed on the basis of the consent of the person concerned or some other legitimate basis, laid down by law, either in this Regulation or in other Union or Member State law as referred to in this Regulation. In case of a child or a person lacking legal capacity, relevant Union or Member State law should determine the conditions under which consent is given or authorised by that person.

(31a) Wherever this Regulation refers to a legal basis or a legislative measure, this does not necessarily require a legislative act adopted by a parliament, without prejudice to requirements pursuant the constitutional order of the Member State concerned, however such legal basis or legislative measure should be clear and precise and its application foreseeable for those subject to it as required by the case law of the Court of Justice of the European Union and the European Court on Human Rights.

(25aa) 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 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.

(31) In order for processing to be lawful, personal data should be processed on the basis of the consent of the person concerned or some other legitimate basis, laid down by law, either in this Regulation or in other Union or Member State law as referred to in this Regulation. In case of a child or a person lacking legal capacity, relevant Union or Member State law should determine the conditions under which consent is given or authorised by that person.

(31a) Wherever this Regulation refers to a legal basis or a legislative measure, this does not necessarily require a legislative act adopted by a parliament, without prejudice to requirements pursuant the constitutional order of the Member State concerned, however such legal basis or legislative measure should be clear and precise and its application foreseeable for those subject to it as required by the case law of the Court of Justice of the European Union and the European Court on Human Rights.

- **Council text**
- **31 a) optional**
### Recital 32

Where processing is based on the data subject’s consent, the controller should have the burden of proving that the data subject has given the consent to the processing operation. In particular in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware that and to what extent consent is given.

#### Council or Commission text, not the Parliament text

Where processing is based on the data subject’s consent, the controller should have the burden of proving that the data subject has given the consent to the processing operation. In particular in the context of a written declaration on another matter, safeguards should ensure that the data subject is aware that and to what extent consent is given. To comply with the principle of data minimisation, the burden of proof should not be understood as requiring the positive identification of data subjects unless necessary. Similar to civil law terms (e.g. Council Directive 93/13/EEC 44a), data protection policies should be as clear and transparent as possible. They should not contain hidden or disadvantageous clauses. Consent cannot be given for the processing of personal data of third persons.

### Recital 40

(40) 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 this other purpose or should base the processing on another legitimate ground for lawful processing, in particular where provided by public law or the law of the Member State to which the controller is subject.

#### Council text

40) The processing of personal data for other purposes than the purposes for which the data have been initially collected should be only allowed where the processing is compatible with those purposes for which the data have been initially collected. 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 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. The legal basis provided by Union or Member State law for the collection and processing of personal data may also provide a legal basis for further processing for other purposes if these purposes are in line with the assigned task and the controller is entitled legally to collect the data for these other purposes.
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Recital 53

(53) Any person should have the right to have personal data concerning them rectified and a ‘right to be forgotten’ where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. This right is particularly relevant, when the data subject has given their consent as a child, when not being fully aware of the risks involved by the processing, and later wants to remove such personal data especially on the Internet. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for reasons of public interest in the area of public health, for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them.

(53) Any person should have the right to have personal data concerning them rectified and a ‘right to be erased’ where the retention of such data is not in compliance with this Regulation. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for reasons of public interest in the area of public health, for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them. Also, the right to erasure should not apply when the retention of personal data is necessary for the performance of a contract with the data subject, or when there is a legal obligation to retain this data.

(53) A natural person should have the right to have personal data concerning them rectified and a ‘right to be forgotten’ where the retention of such data is not in compliance with this Regulation or with Union or Member State law to which the controller is subject. In particular, data subjects should have the right that their personal data are erased and no longer processed, where the data are no longer necessary in relation to the purposes for which the data are collected or otherwise processed, where data subjects have withdrawn their consent for processing or where they object to the processing of personal data concerning them or where the processing of their personal data otherwise does not comply with this Regulation. However, the further retention of the data should be allowed where it is necessary for historical, statistical and scientific research purposes, for reasons of public interest in the area of public health, for exercising the right of freedom of expression, when required by law or where there is a reason to restrict the processing of the data instead of erasing them. Also, the right to erasure should not apply when the retention of personal data is necessary for the performance of a contract with the data subject, or when there is a legal obligation to retain this data.

In order to ascertain whether a purpose of further processing is compatible with the purpose for which the data are initially collected, the controller, after having met all the requirements for the lawfulness of the original processing, should take into account inter alia any link between those purposes and the purposes of the intended further processing, the context in which the data have been collected, including the reasonable expectations of the data subject as to their further use, the nature of the personal data, the consequences of the intended further processing for data subjects, and the existence of appropriate safeguards in both the original and intended processing operations. Where the intended 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 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.

\[Council text\]
European Commission proposal
COM (2012)0011
January, 25 2012

Parliament Position / First Reading
March, 12 2014

Council General Approach
June, 15 2015

German Data Forum
Recommendations

<table>
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<tr>
<th>Recital 125</th>
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<tr>
<td><strong>(125)</strong> The processing of personal data for the purposes of historical, statistical or scientific research should, in order to be lawful, also respect other relevant legislation such as on clinical trials.</td>
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(125) The processing of personal data for the purposes of historical, statistical or scientific research should, in order to be lawful, also respect other relevant legislation such as on clinical trials.

(125a) Personal data may also be processed subsequently by archive services whose main or mandatory task is to collect, conserve, provide information about, exploit and disseminate archives in the public interest. Member State legislation should reconcile the right to the protection of personal data with the rules on archives and on public access to administrative information. Member States should encourage the drafting, in particular by the European Archives Group, of rules to guarantee the confidentiality of data vis-à-vis third parties and the authenticity, integrity and proper conservation of data.

| (125) The processing of personal data for the purposes of historical, statistical or scientific purposes or for archiving purposes in the public interest, for historical, statistical and scientific purposes or for the establishment, exercise or defence of legal claims. |

| (125) The processing of personal data for the purposes of historical, statistical or scientific purposes and for archiving purposes in the public interest should, in addition to the general principles and specific rules of this Regulation, in particular as regards the conditions for lawful processing, also comply with respect to other relevant legislation such as on clinical trials. The further processing of personal data for historical, statistical and scientific purposes and for archiving purposes in the public interest should not be considered incompatible with the purposes for which the data are initially collected and may be processed for those purposes for a longer period than necessary for that initial purpose. Member States should be authorised to provide, under specific conditions and in the presence of appropriate safeguards for data subjects, specifications and derogations to the information requirements and the rights to access, rectification, erasure, to be forgotten, restriction of processing and on the right to data portability and the right to object when processing personal data for historical, statistical or scientific purposes and for archiving purposes. The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific processing along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles. |

| (125aa) By coupling information from registries, researchers can obtain new knowledge of great value when it comes to e.g. widespread diseases as cardiovascular disease, cancer, depression etc. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about long-term impact of a number of social condi- |

| ▶ Council text |

| ▶ 125 aa) Council text |
tions e.g. unemployment, education, and the coupling of this information to other life conditions. Research results obtained on the basis of registries provide solid, high quality knowledge, which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people, and improve the efficiency of social services etc. In order to facilitate scientific research, personal data can be processed for scientific purposes subject to appropriate conditions and safeguards set out in Member State or Union law. Hence consent from the data subject should not be necessary for each further processing for scientific purposes.

(125b) ‘The importance of archives for the understanding of the history and culture of Europe’ and ‘that well-kept and accessible archives contribute to the democratic function of our societies’, were underlined by Council Resolution of 6 May 2003 on archives in the Member States.

Where personal data are processed for archiving purposes, this Regulation should also apply to that processing, bearing in mind that this Regulation should not apply to deceased persons. Public authorities or public or private bodies that hold records of public interest should be services which, pursuant to Union or Member State law, have a legal obligation to acquire, preserve, appraise, arrange, describe, communicate, promote, disseminate and provide access to records of enduring value for general public interest. Member States should also be authorised to provide that personal data may be further processed for archiving purposes, for example with a view to providing specific information related to the political behavior under former totalitarian state regimes.

▶ 125 b) Council text
<table>
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<tr>
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<tr>
<td>Recital 126</td>
<td>Scientific research for the purposes of this Regulation should include fundamental research, applied research, and privately funded research and in addition should take into account the Union’s objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area.</td>
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<td>Recital 132a</td>
<td>The processing of personal data concerning health, as a special category of data, may be necessary for reasons of historical, statistical or scientific research. Therefore this Regulation foresees an exemption from the requirement of consent in cases of research that serves a high public interest.</td>
<td>n/a</td>
<td>Parliament text</td>
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<td></td>
<td>Where personal data are processed for scientific purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, processing of personal data for scientific purposes should include fundamental research, applied research, privately funded research and in addition should take into account the Union’s objective under Article 179(1) of the Treaty on the Functioning of the European Union of achieving a European Research Area. Scientific purposes should also include studies conducted in the public interest in the area of public health. To meet the specificities of processing personal data for scientific purposes specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific purposes. If the result of scientific research in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures.</td>
<td></td>
<td>Parliament text as it strengthens the primacy of science and research</td>
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## Article 1 (2a) – Subject matter and objectives

2a. Member States may maintain or introduce more specific provisions to adapt the application of the rules of this Regulation with regard to the processing of personal data for compliance with a legal obligation or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or for other specific processing situations as provided for in Article 6(1)(c) and (e) by determining more precisely specific requirements for the processing and other measures to ensure lawful and fair processing including for other specific processing situations as provided for in Chapter IX.

## Article 4 – Definitions Chapter 1: General Provisions

For the purposes of this Regulation:

1. ‘data subject’ means an identified natural person or a natural person 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 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;

2. ‘personal data’ means any information relating to a data subject;

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;

2b. ‘encrypted data’ means personal data, which through technological protection measures is rendered unintelligible to any person who is not authorised to access it;

For the purposes of this Regulation:

1. ‘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;

2. ‘data subject’ means an identified natural person or a natural person 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 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;

(2) deleted

For the purposes of this Regulation:

1. deleted

(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 identity of that person;
(3) ‘processing’ means any operation or set of operations which is performed upon personal data or sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination (…) restriction, erasure or destruction;

(3a) ‘restriction of processing’ means the marking of stored personal data with the aim of limiting their processing in the future;

(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-attribute to an identified or identifiable person (…)

(4) ‘filing system’ means any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralized or dispersed on a functional or geographical basis;

(5) ‘controller’ means the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes (…) and means of the processing of personal data; where the purposes (…) and means of processing are determined by Union law or Member State law, the controller or the specific criteria

(6) ‘processor’ means a natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller,

(7) ‘recipient’ means a natural or legal person, public authority, agency or any other body (…) to which the personal data are disclosed, whether a third party or not; however, authorities which may receive data in the framework of a particular inquiry shall not be regarded a recipients;
### Article 5 – Principles relating to personal data processing

#### Chapter 2: Principles

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(8) ‘the data subject’s consent’ means any freely given, specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed;

(11) ‘biometric data’ means any data relating to the physical, physiological or behavioral characteristics of an individual which allow his or her unique identification, such as facial images, or dactyloscopic data;

(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;

(8) ‘the data subject’s consent’ means any freely given, specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed;

(11) ‘biometric data’ means any personal data relating to the physical, physiological or behavioral characteristics of an individual which allow his or her unique identification, such as facial images, or dactyloscopic data;

(12) ‘data concerning health’ means any personal data which relate to the physical or mental health of an individual, or to the provision of health services to the individual;

(8) ‘the data subject’s consent’ means any freely given, specific and informed (…) indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed;

(11) ‘biometric data’ means any personal data resulting from specific technical processing relating to the physical, physiological or behavioral characteristics of an individual which allows or confirms the unique identification of that individual, such as facial images, or dactyloscopic data;

(12) ‘data concerning health’ means data related to the physical or mental health of an individual, which reveal information about his or her health;

(12a) ‘profiling’ means any form of automated processing of personal data consisting of using those data to evaluate personal aspects relating to a natural person, in particular to analyse and predict aspects concerning performance at work, economic situation, health, personal preferences, or interests, reliability or behavior, location or movements;

(8) Parliament text

(8) Council text, however the other options are acceptable

(a) Parliament text

(b) Council text!! (highly relevant)

(c) Council text!! (relevant)

(d) Parliament text
are processed, are erased or rectified without delay;
(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;

(f) processed under the responsibility and liability of the controller, who shall ensure and demonstrate for each processing operation the compliance with the provisions of this Regulation.

1. Where Article 6(1)(a) applies the controller shall be able to demonstrate that unambiguous consent was given by the data subject.

1a. Where Article 9(2)(a) applies, the controller shall be able to demonstrate that explicit consent was given by the data subject.

2. If the data subject's consent is to be given in the context of a written declaration which also concerns another matter, the requirement to give consent must be presented distinguishable in its appearance from this other matter.

2. If the data subject's consent is given in the context of a written declaration which also concerns another matter, the requirement to give consent must be presented clearly distinguishable in its appearance from this other matter. Provisions on the data subject’s consent which are partly in violation of this Regulation are fully void.

1. Where Article 6(1)(a) applies the controller shall be able to demonstrate that unambiguous consent was given by the data subject.

1a. Where Article 9(2)(a) applies, the controller shall be able to demonstrate that explicit consent was given by the data subject.

2. If the data subject’s consent is to be given in the context of a written declaration which also concerns other matters, the request for consent must be presented in a manner which is clearly distinguishable (…) from the other matters, in an intelligible and easily accessible form, using clear and plain language.
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3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal.

4. Consent shall not provide a legal basis for processing, where there is a significant imbalance between the position of the data subject and the controller.

Article 9 (2h, i) – Processing of special categories of personal data

(h) processing of data concerning health is necessary for health purposes and subject to the conditions and safeguards referred to in Article 81; or

(h) processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union law or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 4; or

(ha) (…);

(hb) processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union law or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject; or
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(i) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83; or

(ii) processing is necessary for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83; or

(iia) processing is necessary for archiving purposes in the public interest or historical, statistical or scientific (…) purposes and subject to the conditions and safeguards laid down in Union or Member State law, including those referred to in Article 83.

**Article 19 Right to object**

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.

**Article 38 – Codes of conduct**

1. The Member States, the supervisory authorities and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper application of this Regulation, taking account of the specific features of the various data processing sectors, in particular in relation to:
   (a) fair and transparent data processing
   (b) the collection of data;
   (c) the information of the public and of data subjects
   (d) requests of data subjects in exercise of their rights
   (e) information and protection of children
   (f) transfer of data to third countries or international organisations
   (g) mechanisms for monitoring and ensuring compliance with the code by the controllers adherent to it;
   (h) out-of-court proceedings and other dispute resolution procedures for resolving disputes between controllers and data subjects with respect to the processing of personal data, without prejudice to the rights of the data subjects pursuant to Articles 73 and 75.

NEW PROPOSAL:
Scientific supervisory board should be created!

1a. Associations and other bodies representing categories of controllers or processors may prepare codes of conduct or amend or extend such codes for the purpose of specifying the application of provisions of this Regulation, such as:
   (a) fair and transparent data processing;
   (aa) the legitimate interests pursued by controllers in specific contexts;
   (b) the collection of data;
   (bb) the pseudonymisation of personal data;
   (c) the information of the public and of data subjects;
   (d) the exercise of the rights of data subjects;
   (e) information and protection of children and the way to collect the parent’s and guardian’s consent;
   (ee) measures and procedures referred to in Articles 22 and 23 and measures to ensure security of processing referred to in Article 30;
   (ef) notification of personal data breaches to supervisory authorities and communication of such breaches to
2. Associations and other bodies representing categories of controllers or processors in one Member State which intend to draw up codes of conduct or to amend or extend existing codes of conduct may submit them to an opinion of the supervisory authority in that Member State. The supervisory authority may give an opinion whether the draft code of conduct or the amendment is in compliance with this Regulation. The supervisory authority shall seek the views of data subjects or their representatives on these drafts.

2. Associations and other bodies representing categories of controllers or processors in one Member State which intend to draw up codes of conduct or to amend or extend existing codes of conduct may submit them to an opinion of the supervisory authority in that Member State. The supervisory authority shall without undue delay give an opinion on whether the processing under the draft code of conduct or the amendment is in compliance with this Regulation. The supervisory authority shall seek the views of data subjects or their representatives on these drafts.

2a. Where the opinion referred to in paragraph 2 confirms that the code of conduct, or amended or extended code, is in compliance with this Regulation and the code is approved, and if the code of conduct does not relate to processing activities in several Member States, the supervisory authority shall register the code and publish the details thereof.

2b. Where the draft code of conduct relates to processing activities in several Member States, the supervisory authority shall:

- give an opinion whether the draft code of conduct or the amendment is in compliance with this Regulation
- seek the views of data subjects or their representatives on these drafts.

1b. Such a code of conduct shall contain mechanisms which enable the body referred to in paragraph 1 of article 38a to carry out the mandatory monitoring of compliance with its provisions by the controllers or processors which undertake to apply it, without prejudice to the tasks and powers of the supervisory authority which is competent pursuant to Article 51 or 51a.

1ab. In addition to adherence by controller or processor subject to the regulation, codes of conduct approved pursuant to paragraph 2 may also be adhered to by controllers or processors that are not subject to this Regulation according to Article 3 in order to provide appropriate safeguards within the framework of personal data transfers to third countries or international organizations under the terms referred to in Article 42(2)(d). Such controllers or processors shall make binding and enforceable commitments, via contractual instruments or otherwise, to apply those appropriate safeguards including as regards data subjects’ rights.
### Article 38a – Monitoring of approved codes of conduct


3. Associations and other bodies representing categories of controllers or processors in several Member States may submit draft codes of conduct and amendments or extensions to existing codes of conduct to the Commission.

4. The Commission may adopt implementing acts for deciding that the codes of conduct and amendments or extensions to existing codes of conduct submitted to it pursuant to paragraph 3 have general validity within the Union. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 87(2).

5. The Commission shall ensure appropriate publicity for the codes which have been decided as having general validity in accordance with paragraph 4.

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3. Where the opinion referred to in paragraph 2b confirms that the codes of conduct, or amended or extensions to existing codes of conduct submitted to it pursuant to paragraph 3 are in line with this Regulation and have general validity within the Union. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 87(2).

4. The Commission may adopt implementing acts for deciding that the approved codes of conduct and amendments or extensions to existing approved codes of conduct submitted to it pursuant to paragraph 3 have general validity within the Union. Those implementing acts shall confer enforceable rights on data subjects.

5. The Commission shall ensure appropriate publicity for the codes which have been decided as having general validity in accordance with paragraph 4.

5a. The European Data Protection Board shall collect all approved codes of conduct and amendments thereto in a register and shall make them publicly available through any appropriate means, such as through the European E-Justice Portal.

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1. Without prejudice to the tasks and powers of the competent supervisory authority under Articles 52 and 53, the monitoring of compliance with a code of conduct pursuant to Article 38 (1b), may be carried out by a body which has an appropriate level of expertise in relation to the subject-matter of the code and is accredited for this purpose by the competent supervisory authority.

2. A body referred to in paragraph 1 may be accredited for this purpose if:
(a) it has demonstrated its independence and expertise in relation to the subject-matter of the code to the satisfaction of the competent supervisory authority;

(b) it has established procedures which allow it to assess the eligibility of controllers and processors concerned to apply the code, to monitor their compliance with its provisions and to periodically review its operation;

(c) it has established procedures and structures to deal with complaints about infringements of the code or the manner in which the code has been, or is being, implemented by a controller or processor, and to make these procedures and structures transparent to data subjects and the public;

(d) it demonstrates to the satisfaction of the competent supervisory authority that its tasks and duties do not result in a conflict of interests.

3. The competent supervisory authority shall submit the draft criteria for accreditation of a body referred to in paragraph 1 to the European Data Protection Board pursuant to the consistency mechanism referred to in Article 57.

4. Without prejudice to the provisions of Chapter VIII, a body referred to in paragraph 1 may, subject to adequate safeguards, take appropriate action in cases of infringement of the code by a controller or processor, including suspension or exclusion of the controller or processor concerned from the code. It shall inform the competent supervisory authority of such actions and the reasons for taking them.

5. The competent supervisory authority shall revoke the accreditation of a body referred to in paragraph 1 if the conditions for accreditation are not, or no longer, met or actions taken by the body are not in compliance with this Regulation.

6. This article shall not apply to the processing of personal data carried out by public authorities and bodies.
1. The Member States and the Commission shall encourage, in particular at European level, the establishment of data protection certification mechanisms and of data protection seals and marks, allowing data subjects to quickly assess the level of data protection provided by controllers and processors. The data protection certifications mechanisms shall contribute to the proper application of this Regulation, taking account of the specific features of the various sectors and different processing operations.

1a. Any controller or processor may request any supervisory authority in the Union, for a reasonable fee taking into account the administrative costs, to that the processing of personal data is performed in compliance with this Regulation, in particular with the principles set out in Article 5, 23 and 30, the obligations of the controller and the processor, and the data subject’s rights.

1b. The certification shall be voluntary, affordable, and available via a process that is transparent and not unduly burdensome.

1c. The supervisory authorities and the European Data Protection Board shall cooperate under the consistency mechanism pursuant to Article 57 to guarantee a harmonised data protection certification mechanism including harmonised fees within the Union.

1d. During the certification procedure, the supervisory authority may accredit specialised third party auditors to carry out the auditing of the controller or the processor on their behalf. Third party auditors shall have sufficiently qualified staff, be impartial and free from any conflict of interests regarding their duties. Supervisory authorities shall revoke accreditation, if there are reasons to believe that the auditor does not fulfil its duties correctly. The final certification shall be provided by the supervisory authority.

1e. Supervisory authorities shall grant controllers and processors, who pursuant to the auditing have been certified that they process personal data in compliance with this Regulation, the standardised data protection mark named ‘European Data Protection Seal’.

1f. The ‘European Data Protection Seal’ shall be valid for as long as the data processing operations of the certified controller or processor continue to fully comply with this Regulation.

1g. Notwithstanding paragraph 1f, the certification shall be valid for maximum five years.

1. The Member States, the European Data Protection Board and the Commission shall encourage, in particular at Union level, the establishment of data protection certification mechanisms and of data protection seals and marks for the purpose of demonstrating compliance with this Regulation of processing operations carried out by controllers and processors. The specific needs of micro, small and medium-sized enterprises shall be taken into account.

1a. In addition to adherence by controllers or processors subject to this Regulation, data protection certification mechanisms, seals or marks approved pursuant to paragraph 2a may also be established for the purpose of demonstrating the existence of appropriate safeguards provided by controllers or processors that are not subject to this Regulation according to Article 3 within the framework of personal data transfers to third countries or international organisations under the terms referred to in Article 42(2) (e). Such controllers or processors shall make binding and enforceable commitments, via contractual instruments or otherwise, to apply those appropriate safeguards, including as regards data subjects’ rights.
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<td>2. 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 data protection certification mechanisms referred to in paragraph 1, including conditions for granting and withdrawal, and requirements for recognition within the Union and in third countries.</td>
<td>1h. The European Data Protection Board shall establish a public electronic register in which all valid and invalid certificates which have been issued in the Member States can be viewed by the public.</td>
<td>2. A certification pursuant to this Article does not reduce the responsibility of the controller or the processor for compliance with this Regulation and is without prejudice to the tasks and powers of the supervisory authority which is competent pursuant to Article 51 or 51a.</td>
<td>2a. A certification pursuant to this Article shall be issued by the certification bodies referred to in Article 39a, or where applicable, by the competent supervisory authority on the basis of the criteria approved by the competent supervisory authority or, pursuant to Article 57, the European Data Protection Board.</td>
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<td>3. The Commission may lay down technical standards for certification mechanisms and data protection seals and marks and mechanisms to promote and recognize certification mechanisms and data protection seals and marks. Those implementing acts shall be adopted in accordance with the examination procedure set out in Article 87(2).</td>
<td>1i. The European Data Protection Board may on its own initiative certify that a data protection-enhancing technical standard is compliant with this Regulation.</td>
<td>2. The Commission shall be empowered to adopt, after requesting an opinion of the European Data Protection Board and consulting with stakeholders, in particular industry and non-governmental organisations, delegated acts in accordance with Article 86 for the purpose of further specifying the criteria and requirements for the data protection certification mechanisms referred to in paragraphs 1a to 1h, including requirements for accreditation of auditors, conditions for granting and withdrawal, and requirements for recognition within the Union and in third countries. Those delegated acts shall confer enforceable rights on data subjects.</td>
<td>2h. The European Data Protection Board shall establish a public electronic register in which all valid and invalid certificates which have been issued in the Member States can be viewed by the public.</td>
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<td>3. The controller or processor which submits its processing to the certification mechanism shall provide the certification body referred to in Article 39a, or where applicable, the competent supervisory authority, with all information and access to its processing activities which are necessary to conduct the certification procedure.</td>
<td>3. The controller or processor which submits its processing to the certification mechanism shall provide the certification body referred to in Article 39a, or where applicable, the competent supervisory authority, with all information and access to its processing activities which are necessary to conduct the certification procedure.</td>
<td>4. The certification shall be issued to a controller or processor for a maximum period of 3 years and may be renewed under the same conditions as long as the relevant requirements continue to be met. It shall be withdrawn by the certification bodies referred to in Article 39a, or where applicable, by the competent supervisory authority where the requirements for the certification are not or no longer met.</td>
<td>3. The controller or processor which submits its processing to the certification mechanism shall provide the certification body referred to in Article 39a, or where applicable, the competent supervisory authority, with all information and access to its processing activities which are necessary to conduct the certification procedure.</td>
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<td>5. The European Data Protection Board shall collect all certification mechanisms and data protection seals in a register and shall make them publicly available through any appropriate means, such as through the European E-Justice Portal.</td>
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Article 39a
Certification body and procedure

1. Without prejudice to the tasks and powers of the competent supervisory authority under Articles 52 and 53, the certification shall be issued and renewed by a certification body which has an appropriate level of expertise in relation to data protection. Each Member State shall provide whether these certification bodies are accredited by:
   (a) the supervisory authority which is competent according to Article 51 or 51a; and/or
   (b) the National Accreditation Body named in accordance with Regulation (EC) 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements of accreditation and market surveillance relating to the marketing of products in compliance with EN-ISO/IEC 17065/2012 and with the additional requirements established by the supervisory authority which is competent according to Article 51 or 51a.

2. The certification body referred to in paragraph 1 may be accredited for this purpose only if:
   (a) it has demonstrated its independence and expertise in relation to the subject-matter of the certification to the satisfaction of the competent supervisory authority;
   (aa) it has undertaken to respect the criteria referred to in paragraph 2a of Article 39 and approved by the supervisory authority which is competent according to Article 51 or 51a or, pursuant to Article 57, the European Data Protection Board;
   (b) it has established procedures for the issue, periodic review and withdrawal of data protection seals and marks;
   (bb) it has established procedures and structures to deal with complaints about infringements of the certification or the manner in which the certification has been, or is being, implemented by the controller or processor, and to make these procedures and structures transparent to data subjects and the public;
   (c) it demonstrates to the satisfaction of the competent supervisory authority that its tasks and duties do not result in a conflict of interests.

3. The accreditation of the certification bodies referred to in paragraph 1 shall take place on the basis of criteria approved by the supervisory authority which is competent.
according to Article 51 or 51a or, pursuant to Article 57, the European Data Protection Board. In case of an accreditation pursuant to point (b) of paragraph 1, these requirements complement those envisaged in Regulation 765/2008 and the technical rules that describe the methods and procedures of the certification bodies.

4. The certification body referred to in paragraph 1 shall be responsible for the proper assessment leading to the certification or the withdrawal of such certification without prejudice to the responsibility of the controller or processor for compliance with this Regulation. The accreditation is issued for a maximum period of five years and can be renewed in the same conditions as long as the body meets the requirements.

5. The certification body referred to in paragraph 1 shall provide the competent supervisory authority with the reasons for granting or withdrawing the requested certification.

6. The requirements referred to in paragraph 3, the criteria referred to in paragraph 2a of Article 39 shall be made public by the supervisory authority in an easily accessible form. The supervisory authorities shall also transmit these to the European Data Protection Board. The European Data Protection Board shall collect all certification mechanisms and data protection seals in a register and shall make them publicly available through any appropriate means, such as through the European E-Justice Portal.

6a. Without prejudice to the provisions of Chapter VIII, the competent supervisory authority or the National Accreditation Body shall revoke the accreditation it granted to a certification body referred to in paragraph 1 if the conditions for accreditation are not, or no longer, met or actions taken by the body are not in compliance with this Regulation.

7. The Commission shall be empowered to adopt delegated acts in accordance with Article 86, for the purpose of (…) specifying the criteria and requirements to be taken into account for the data protection certification mechanisms referred to in paragraph 1, [including conditions for granting and revocation, and requirements for recognition of the certification and the requirements for a standardised ‘Euro-
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<tr>
<th><strong>European Commission proposal</strong></th>
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**Article 64 European Data Protection Board**

1a. European Data Protection Board is hereby set up.

2. The European Data Protection Board shall be composed of the head of one supervisory authority of each Member State and of the European Data Protection Supervisor.

3. Where in a Member State more than one supervisory authority is responsible for monitoring the application of the provisions pursuant to this Regulation, they shall nominate the head of one of those supervisory authorities as joint representative.

4. The Commission shall have the right to participate in the activities and meetings of the European Data Protection Board and shall designate a representative. The chair of the European Data Protection Board shall, without delay, inform the Commission on all activities of the European Data Protection Board.

1a. The European Data Protection Board is hereby set up established as body of the Union and shall have legal personality.

1b. The European Data Protection Board shall be represented by its Chair.

2. The European Data Protection Board shall be composed of the head of one supervisory authority of each Member State and of the European Data Protection Supervisor.

3. Where in a Member State more than one supervisory authority is responsible for monitoring the application of the provisions pursuant to this Regulation, a joint representative shall be appointed in accordance with the national law of that Member State.

4. The Commission and the European Data Protection Supervisor or his/her representative shall have the right to participate in the activities and meetings of the European Data Protection Board without voting right. The Commission shall designate a representative. The chair of the European Data Protection Board shall, communicate to the Commission the activities of the European Data Protection Board.

**NEW PROPOSAL:**

Scientific advisory board should be created!
Article 836// Chapter 9: Provisions relating to specific data processing situations

1. Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes only if:
   (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;
   (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.

2. Bodies conducting historical, statistical or scientific research may publish or otherwise publicly disclose personal data only if:
   (a) the data subject has given consent, subject to the conditions laid down in Article 7;
   (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
   (c) the data subject has made the data public.

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.

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 Articles 14a(1) and (2), 15, 16, 17, 17a, 17b, 18 and 19, insofar as such derogation is necessary for the fulfilment of these purposes.

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.

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 these measures prevent achieving the purpose of the processing and such purpose cannot be otherwise fulfilled within reasonable means.

3. (…)
Overview of research-relevant sections:

- Recital 23
- Recital 25
- Recital 31
- Recital 32
- Recital 40
- Recital 53
- Recital 125
- Recital 126
- Recital 132a
- Chapter 1: General Provisions
  - Article 1: Subject matter and objectives
  - Article 4: Definitions
- Chapter 2: Principles
  - Article 5: Principles relating to personal data processing
  - Article 7: Conditions for consent
  - Article 9: Processing of special categories of personal data
- Chapter 3: Rights of the Data Subject
  - Article 19: Right to object
- Chapter 4: Controller and Processor
  - Article 38: Codes of conduct
  - Article 38a: Monitoring of approved codes of conduct
  - Article 38/39 a) Certification
- Chapter 7: Co-operation and Consistency
- Chapter 9: Provisions relating to Specific Data Processing Situations
  - Article 81: Processing of personal data concerning health
  - Article 81a: Processing of personal data concerning health
  - Article 82: Processing in the employment context
  - Article 83: Processing for historical, statistical and scientific research purposes