Protecting health and scientific research in the Data Protection Regulation (2012/0011(COD))

Position of non-commercial research organisations and academics – April 2014

Health and scientific research will be severely threatened if the amendments to Articles 81 and 83 of the Data Protection Regulation adopted by the European Parliament are taken forward. Scientific research generates important benefits by improving our understanding of society, health and disease. If implemented, the amendments would make much research involving personal data at worst illegal, and at best unworkable.

In order to protect valuable research while protecting privacy, we urge:

- **the Council of Ministers to maintain the Commission's text on Articles 81 and 83 and associated provisions when agreeing its general approach;**
- **MEPs to seek a more positive outcome for research in trilogue negotiations; and**
- **the Council of Ministers and European Commission to oppose the European Parliament's amendments to Articles 81 and 83 in trilogue negotiations.**

The original draft Regulation set out a proportionate mechanism for protecting privacy, while enabling health and scientific research to continue. It included a requirement for specific and explicit consent for the use and storage of personal data, but provided an exemption for research, subject to certain safeguards in Article 83. This recognised that individuals' interests can be protected through strong ethical and governance safeguards, such as approval by a research ethics committee.

The European Parliament's amendments to Articles 81 and 83 very significantly reduce the scope of this research exemption. The use of personal data in research without specific consent would be prohibited or become impossible in practice. The requirement for specific consent fails to take account of the fact that this research is subject to ethical approval and strict confidentiality safeguards, and the identity of individuals is often masked.

This would put at risk significant European investments in genetics, cohort studies, biobanks, disease registries and the use of routinely collected data, and associated progress towards understanding society, health, and disease that delivers real patient benefit.

Further information is included on pages two and three, with detailed technical comments on the amendments adopted by the European Parliament provided in Annex A.

QUESTIONS AND ANSWERS

Why are personal data so important for research to improve public health and healthcare?

Personal data, such as individual patient records, provide a vital resource for research for the benefit of society and saving and improving the lives of patients. For example, personal data allow researchers to compare different factors, such as lifestyle, and the incidence of disease at an individual level. These observational studies have led to breakthroughs such as identifying the association between smoking and lung cancer and informing treatment of infection in unborn babies.

How do researchers safeguard confidentiality?

Research using personal data should only take place within a robust ethical and governance framework to ensure that an individual's personal data are only used in research when this is proportionate to the potential benefits for society as a whole. Researchers are given access to personal data only under strict confidentiality controls, which have been effective at preventing misuse and harm to data subjects.

Why will the European Parliament's amendments prevent health research?

LIBE amendments 86, 191 and 194 to Articles 81 and 83 would:

- make it very difficult, if not impossible in practice, to use pseudonymised data concerning health – where an individual's identity is masked to protect privacy – without specific consent; and
- prohibit the use of identifiable personal data in scientific research without specific consent. Researchers only use identifiable data without consent where other approaches are not practicable and this is currently only allowed subject to ethical approval and strict confidentiality safeguards. Sometimes researchers need details such as age, postcode and information on a health condition that together could disclose the identity of an individual, but the study would not be possible without it.

Further explanation of our concerns is provided in Annex A.

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How would data subjects be protected without the European Parliament's amendments?
The amendments are intended to protect data subjects in research but there are other, better ways to achieve this. A rigorous regulatory and governance framework for research already exists, enshrined in national and international laws, and researchers follow guidance built on strong ethical principles. The amendments are therefore not necessary to protect data subjects. However, the Regulation could be strengthened to clarify the important role of existing safeguards, such as project approval by an independent ethics committee.

What type of research would the European Parliament's amendments put at risk?
The amendments will make much health research involving personal data at worst illegal, and at best unworkable. This research has the potential to deliver further gains in our understanding of common chronic diseases that affect large numbers of European patients, such as Alzheimer's disease and cancer.

The amendments will put at risk significant European investments in genetics, cohort studies and the use of routinely collected data, such as:

- The European Prospective Investigation into Cancer and Nutrition (EPIC), the largest study of diet and health ever undertaken, involving over half a million European citizens, which uses broad consent from participants to allow researchers to access relevant data through rigorous governance arrangements.
- The European Medical Information Framework, a €56 million project to link together existing health data from sources across Europe to make this wealth of information available to researchers for studies on obesity and Alzheimer's disease.
- The Human Brain Project, which aims to use existing data to model how the brain works and catalyse a global collaborative effort to understand the human brain and its diseases.

The amendments will also affect research on important economic and societal issues, which often relies on data from a range of sources collected over many years, such as:

- The European Social Survey, which measures opinions and behaviours across more than thirty European countries to inform policy in areas such as health inequalities and economic instability.

In many studies that will be affected, individuals have voluntarily given broad consent for their data to be used in research to further our understanding of society, health and disease. Their valuable contributions could be wasted if the amendments become law.

What steps are needed to protect research and its benefits?
It is vital that the Commission's original research provisions are maintained to ensure that the Regulation strikes an appropriate balance between facilitating the safe and secure use of personal data in research and the rights and interests of individuals.

In order to protect valuable research while protecting privacy, we urge:

- **the Council of Ministers to maintain the Commission's text on Articles 81 and 83 and associated provisions when agreeing its general approach;**
- **MEPs to seek a more positive outcome for research in trilogue negotiations; and**
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What are the next steps in the legislative process?
The amendments adopted by the European Parliament form Parliament's position ahead of the next stage of the legislative process. The Council of Ministers must also agree a position and authorise the Presidency to negotiate on its behalf. Once the Council of Ministers has adopted a position, the European Parliament, Council of Ministers and European Commission can enter the 'trilogue' process to negotiate a final draft to vote on.

Signatories

Academy of Medical Sciences UK
Alexander von Humboldt-Stiftung
Alliance for European Diabetes Research (EURADIA)
Arthritis Research UK
Association of Community Nursing (Spain)
Association of Health Administration (Madrid, Spain)
Association of Health Economy (Spain)
Association of Medical Research Charities
Biotechnology and Biological Sciences Research Council
Breast Cancer Campaign
British Association for the study of the Liver
British Heart Foundation
British Society of Gastroenterology
Cancer Research UK
Czech Medical Academy
Deutsche Zentren der Gesundheitsforschung
Deutsche Forschungsgemeinschaft
Deutscher Akademischer Austauschdienst
Diabetes UK
Economic and Social Research Council
EGAN (Patients Network for Medical Research and Health)
Engineering and Physical Sciences Research Council
Epilepsy Research UK
EUROCAT: European Surveillance of Congenital Anomalies
EuroCoord
European Academy of Allergology and Clinical Immunology
European Academies Science Advisory Council
European Association of Research Managers and Administrators
European Association for the Study of Diabetes
European League against Rheumatism
European Organisation for Research and Treatment of Cancer (EORTC)
European University Association
Farr Institute of Health Informatics Research
Federation of European Academies of Medicine
Fraunhofer-Gesellschaft
French National Academy of Medicine
Genetic Alliance UK
German National Academy of Sciences Leopoldina
Global Alliance for Genomics and Health
Health and Social Care, Northern Ireland
Health Law Association (Spain)
Health Research Board (Ireland)
Helmholtz Association
Hipatia (Spain)
Hochschulrektorenkonferenz
Hungarian Academy of Sciences
Independent Cancer Patients' Voice
Inserm
Institut Pasteur
Institute of Cancer Research
Intensive Care Society
International Cancer Genome Consortium
Irish Universities Association
Italian National Academy of Medicine
Leukaemia & Lymphoma Research
Leibniz-Gemeinschaft
Macmillan Cancer Support
Max-Planck-Gesellschaft
Medical Research Council
Medical Schools Council
Motor Neurone Disease Association
Natural Environment Research Council
Nederlandse Federatie van Universitair Medische Centra
NHS European Office
Northern Ireland Biobank
Nuffield Foundation
Parkinson's UK
PHG Foundation
Public Health Association (Canary Islands, Spain)
Public Health Association (Catalonia, Balearic Islands, Spain)
Public Health Association (Madrid, Spain)
Public Population Project in Genomics and Society
Psychiatric Epidemiological Association (Spain)
Research Councils UK
Royal College of Physicians
Royal College of Surgeons
Royal Society of Edinburgh
Russell Group
Science Europe Medical Sciences Committee
Spanish Environmental Health Association
Spanish Network of Primary Health Care
Spanish Society of Epidemiology
UK Higher Education International Unit
UKCRC Registered CTUs Network
United European Gastroenterology
Unique (Understanding Chromosome Disorders)
Universities UK
University of Salford
Vetenskapsrådet / Swedish Research Council
VolkswagenStiftung
VSOP (Association of Cooperating Parent and Patient Organisations)
Wellcome Trust
Wellcome Trust Sanger Institute
Wissenschaftsrat
Yorkshire Cancer Research
ZonMw / The Netherlands Organisation for Health Research and Development

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The Academy of Medical Sciences
Alexander von Humboldt Stiftung/Foundation
EURADIA Alliance for European Diabetes Research
Arthritis Research UK
Asociación de Enfermería Comunitaria
AMAS
AES Asociación de Economía de la Salud
amrc Association of Medical Research Charities
BBSRC bioscience for the future
breast cancer campaign Research that saves lives
BASL British Association for the study of the Liver
British Heart Foundation
bsg British Society of Gastroenterology Research
Cancer Research UK
Česká lékařská akademie
DZG Deutsche Zentren der Gesundheitsforschung
DFG Deutsche Forschungsgemeinschaft
DIABETES UK CARE. CONNECT. CAMPAIGN.
DAAD
E·S·R·C Economic & Social Research Council
EGAN Patients Network for Medical Research and Health
EPSRC Pioneering research and skills
epilepsy research uk
eurocat european surveillance of congenital anomalies
EuroCoord
EAACI European Academy of Allergy and Clinical Immunology
European Academies easac Science Advisory Council
EARMA European Association of Research Managers and Administrators
EASD European Association for the Study of Diabetes
eular
EORTC The future of cancer therapy
EUA European University Association
Farr The Farr Institute of Health Informatics Research
FEAM Federation of European Academies of Medicine
Fraunhofer
Académie nationale de Médecine
Genetic Alliance UK Supporting. Campaigning. Uniting.
Leopoldina Nationale Akademie der Wissenschaften
Global Alliance for Genomics and Health (GA4GH)
HSC Health and Social Care
JS Juristas de la Salud
HRB Health Research Board
HELMHOLTZ ASSOCIATION
HRK German Rectors' Conference
Magyar Tudományos Akadémia 1825
independent cancer patients' voice www.independentcancerpatientsvoice.org.uk
Instituts thématiques
Inserm Institut national de la santé et de la recherche médicale
Institut Pasteur
ICR The Institute of Cancer Research
intensive care society care when it matters
International Cancer Genome Consortium
iua IRISH UNIVERSITIES ASSOCIATION
ACC MED ACCADEMIA NAZIONALE DI MEDICINA
LEUKAEMIA & LYMPHOMA RESEARCH Beating Blood Cancers
Leibniz Leibniz Association
WE ARE MACMILLAN. CANCER SUPPORT
Max-Planck-Gesellschaft
MRC Medical Research Council
Medical Schools Council


mnda
motor neurone disease association
NERC
SCIENCE OF THE ENVIRONMENT
NFU
NEDERLANDSE FEDERATIE VAN UNIVERSITAIR MEDISCHE CENTRA
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Sociedad Española de Epidemiología Psiquiátrica
RESEARCH COUNCILS UK
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THE ROYAL SOCIETY OF EDINBURGH
RUSSELL INTERNATIONAL EXCELLENCE GROUP
SCIENCE EUROPE
Medical Sciences Committee
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Red Española de Atención Primaria
SOCIEDAD ESPAÑOLA DE EPIDEMIOLOGIA
Global opportunities for UK higher education
international unit
UKCRC Registered Clinical Trials Units
UNITED EUROPEAN GASTROENTEROLOGY
ueg
Understanding chromosome disorders
Unique
Universities UK
University of Salford MANCHESTER
Vetenskapsrådet
VolkswagenStiftung
VSOP
wellcome trust
wellcome trust sanger institute
WR
WISSENSCHAFTSRAT
yorkshire cancer research
ZonMw

ANNEX A

ANALYSIS OF THE EUROPEAN PARLIAMENT'S* AMENDMENTS TO THE GENERAL DATA PROTECTION REGULATION (2012/0011(COD))

March 2014

INDEX TABLE

Issue	Relevant articles, recitals and amendment numbers	Priority
Definition of personal data and regulation of pseudonymous data	Article 4(2) and (2a) (LIBE AM 98); Recital 23 (LIBE AM 6) Article 6(f) (LIBE AM 100); Recital 38 (LIBE AM 15)	**** critical**
Other definitions	Article 4(10) and (12) (LIBE AM 98)	
Data storage	Article 5(e) (LIBE AM AM 99)	
Secondary processing	Article 6(4) (LIBE AM 100)); Article 7(4) (LIBE AM 101); Recital 40 (LIBE AM 29)	**** critical**
Right of the data subject to information	Article 14(5)(b) (LIBE AM 110)	
Risk analysis	Article 32a (LIBE AM 127)	
Data protection impact assessments	Article 33 (LIBE AM 129)	
International transfers	Article 42 (LIBE AM 138)	*** high**
Freedom of expression	Article 80 (LIBE AM 189)	
Data concerning health	Article 81 (LIBE AM 191); Recital 123a (LIBE AM 86)	**** critical**
Processing for historical, statistical and scientific research purposes.	Article 83 (LIBE AM 194)	**** critical**

KEY
Text **added** by the LIBE committee is in ***bold italics***
Text **deleted** by the LIBE committee is ~~***struck-through bold italics***~~
Text of **proposed amendments** is in ***bold underlined italics***

*Note: The LIBE committee amendments became the European Parliament position following European Parliament plenary vote

Amdt	Outline	Analysis	Solution
Definition of personal data and regulation of pseudonymous data – ** critical priority			
AM 98 Article 4(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***;	Data that enables indirect identification of individuals is included in the scope of the Regulation. The test of "means reasonably likely to be used" has been deleted from the Commission's text, which means that there is no longer an element of proportionality in determining whether data can lead to the identification of an individual. Pseudonymised data in research are often used in a very robust system with strict organisational, legal and technological safeguards to protect privacy. However, the amendments to Articles 4(2) and 4(2a) and Recital 23 do not recognise this. Article 4(2a) introduces a definition of pseudonymous data. However, this takes an oversimplified view of the use of pseudonymous data in research and does not add clarity. A strict reading of Articles 4(2) and 4(2a) means that even where data are double coded by a separate trusted third party and researchers do not have access to the codes to re-identify individuals, these data would be considered within the scope of the Regulation. Including such robustly pseudonymous data in the scope of the Regulation will impose a disproportionate regulatory burden on this research. This could undermine	Restore "means reasonably likely" test from Commission's proposal in Article 4(2). This will ensure consistency with Recital 23 For example: '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***, by means reasonably likely to be used***, 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;
AM 98Article 4(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;***		

		sophisticated data sharing infrastructure, such as research "safe havens". A risk proportionate approach will also incentivise sophisticated pseudonymisation practices to enhance privacy.	
AM 6 Recital 23	***This Regulation does therefore not concern the processing of such anonymous data, including for statistical and research purposes.***	The Regulation is only intended to apply to "personal data". This amendment to Recital 23 provides additional clarity that anonymous data are out of scope of the Regulation.	Support LIBE amendment 6
AM 100 Article 6(f)	(f) processing is necessary for the purposes of the legitimate interests pursued by ***the a*** ~~***a***~~ controller ***or in case of disclosure, by the third party to whom the data is disclosed, and which meet the reasonable expectations of the data subject based on his or her relationship with the controller***, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data~~***, in particular where the data subject is a child***~~. This shall not apply to processing carried out by public authorities in the performance of their tasks.	LIBE's amendments seek to introduce risk-proportionality where pseudonymous data are processed. However, the amendments create an inconsistency in the rules for the use of pseudonymous data in research and the use of pseudonymous data in other sectors, with other sectors subject to lower standards. For example, Article 6(f) and Recital 38 enable the "legitimate interest" of the data controller to be the legal basis to process pseudonymous data as an alternative to consent. However, to use pseudonymous data in research, researchers would have to comply with Article 6(2) and with the requirements for research in Articles 81 and 83, which set stricter requirements for the use of pseudonymous data.	Oppose LIBE's amendments to Articles 81 and 83 (amendments 86, 191 and 194; see below), to ensure that the use of pseudonymous data in scientific research - which is usually conducted in the public interest - is not subject to a higher level of regulation than other sectors.
AM 15 Recital 38	The legitimate interests of ***the a*** ~~***a***~~ controller, ***or in case of disclosure, by the third party to whom the data is disclosed,*** may provide a legal basis for processing, provided ***that they meet the reasonable expectations of the data subject based on his or her relationship with the controller and*** that the interests or the fundamental rights and freedoms of the data		

	subject are not overriding. This would need careful assessment in particular where the data subject is a child, given that children deserve specific protection. ***Provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, processing limited to pseudonymous data should be presumed to meet the reasonable expectations of the data subject based on his or her relationship with the controller.*** The data subject should have the right to object the processing***~~, on grounds relating to their particular situation and~~*** free of charge. To ensure transparency, the controller should be obliged to explicitly inform the data subject on the legitimate interests pursued and on the right to object, and also be obliged to document these legitimate interests. ***The interests and fundamental rights of the data subject could in particular override the interest of the data controller where personal data are processed in circumstances where data subjects do not reasonably expect further processing.*** Given that it is for the legislator to provide by law the legal basis for public authorities to process data, this legal ground should not apply for the processing by public authorities in the performance of their tasks.		

Other definitions			
AM 98 Article 4(10)	'genetic data' means all ***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 in question, in particular by chromosomal, desoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis or analysis of any other element enabling equivalent information to be obtained;***	The amendment ensures that the definition of genetic data is more consistent with international definitions, such as the United Nations International Declaration on Human Genetic Data, than the Commission's proposal. This provides greater clarity for data controllers on which data are intended to be in the scope of the Regulation compared to the Commission's proposal. Data captured by this definition of genetic data would be captured in the definitions of "data concerning health" and "biometric data", which are both special categories of personal data subject to additional safeguards. It is therefore not clear what a specific definition of "genetic data" is seeking to achieve. It would therefore be acceptable to delete the definition from the text.	In the first instance, delete definition of "genetic data" since this is covered by "data concerning health" and "biometric data". If not, then support LIBE amendment 98 on the basis that it is clearer than the previous version.
AM 98 Article 4(12)	'data concerning health' means any ***personal data ~~information~~*** which relates to the physical or mental health of an individual, or to the provision of health services to the individual;	This amendment provides helpful clarity that data concerning health only relates to personal data, not anonymised data that relates to health. This provides greater clarity for data controllers on which data are intended to be in the scope of the Regulation compared to the Commission's proposal.	Support LIBE amendment 98

Data storage			
AM 99 Article 5(e)	Personal data shall be… …kept in a form which permits ***direct or indirect*** 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 ***or for archive*** purposes in accordance with the rules and conditions of Articles 83 ***and 83a*** and if a periodic review is carried out to assess the necessity to continue the storage, ***and if appropriate technical and organizational measures are put in place to limit access to the data only for these purposes (storage minimisation)***;	This amendment creates a higher threshold for researchers to be able to benefit from the exemption to allow indefinite storage by introducing a requirement for "technical and organizational measures" to be in place. It is unclear what "technical and organizational measures" would be sufficient to comply with this requirement. This will make it difficult for data controllers to know whether they are complying with the requirement, increasing uncertainty about the legality of continuing to store data. Legal uncertainty is likely to make research organisations less willing to continue to store data even where it may be useful for research in the future. This may mean that valuable research resources are lost, wasting the resources investing in them.	Oppose LIBE amendment 99
Secondary processing ** critical priority			
AM 100 Article 6(4)	~~***Where the purpose of further processing is incompatible with the one for which the personal data have been collected, the processing must have a legal basis at least in one of the grounds referred to in points (a) to (e) of paragraph 1. This shall in particular apply to any change of terms and general conditions of a contract.***~~	The Commission's proposal included the concept that a new legal basis is not required where further processing is "not incompatible" with the initial purpose. Research was specified as a "not incompatible" purpose, facilitating the secondary use of data for research. These amendments remove the concept of further processing and "not incompatible" purpose, requiring a new, separate legal basis for any further processing.	Oppose LIBE's amendments to Articles 81 and 83 (amendments 86, 191 and 194; see below), to ensure that the secondary use of data in scientific research can still be conducted where it is not practicable to seek specific consent.
AM 101 Article 7(4)	**Consent shall be purpose-limited and shall lose its validity when the purpose ceases to exist or as soon as the**		

	processing of personal data is no longer necessary for carrying out the purposes for which they were originally collected.	Combined with the amendments to Articles 81 and 83 this will severely restrict the use of existing data in research.	
AM 29 Recital 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 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.~~***		
Right of the data subject to information			
AM 110 Article 14 5(b)	Paragraphs 1 to 4 shall not apply, where… …the data ***are processed for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Articles 81 and 83,*** are not collected from the data subject and the provision of such information proves	The Commission's proposal includes an exemption from notifying data subjects about how their personal data are being used where the data are not collected from the data subject where this involves disproportionate effort. This amendment introduces a further requirement for	Oppose LIBE amendments 110 to Article 14(5)(b) Oppose deletion of research reference in LIBE amendment 25 (Recital 50).

	impossible or would involve a disproportionate effort ***and the controller has published the information for anyone to retrieve***; or	information about the processing to be published for anyone to retrieve, creating a higher threshold for researchers to be able to benefit from the exemption from notifying data subjects. It is unclear what is meant by publishing for "anyone to retrieve". It would be very difficult for a researcher to feel confident that s/he has satisfied this requirement. This will make it difficult for data controllers to know whether they are complying with the requirement, increasing uncertainty about whether they are eligible for the derogation from the notification obligation. This is exacerbated by the deletion of the explicit reference to research as an example of an activity where provision of information may require a disproportionate effort from Recital 50. This legal uncertainty may make research organisations less willing to undertake studies where they are not clear whether they can comply with the requirement. This may prevent studies from taking place.	
AM 25 Recital 50	However, it is not necessary to impose this obligation where the data subject already ***~~disposes~~ knows*** of this information, or where the recording or disclosure of the data is expressly laid down by law, or where the provision of information to the data subject proves impossible or would involve disproportionate efforts. ***~~The latter could be particularly the case where processing is for historical, statistical or scientific research purposes; in this regard, the number of data subjects, the age of the data, and any compensatory measures adopted may be taken into consideration.~~***		
Risk analysis			
AM 127 Article 32a	***1. The controller, or where applicable the processor, shall carry out a risk analysis of the potential impact of the intended data processing on the rights and freedoms of the data subjects, assessing whether its processing operations are likely to present specific risks.***	This amendment introduces the concept of risk analysis and creates a higher risk category for certain processing operations attracting additional regulatory requirements. It is not clear whether most research involving data concerning health is intended to be included in this high risk	The inconsistency between points (b) and (d) in Article 32a(2) should be resolved so that research involving data concerning health does not fall in the high risk category where the data are not processed for taking measures or decisions regarding specific individuals on

	2. The following processing operations are likely to present specific risks: ***(a) …*** ***(b) processing of special categories of personal data as referred to in Article 9(1), location data or data on children or employees in large scale filing systems;*** ***(c)…*** ***(d) processing of personal data for the provision of health care, epidemiological researches, or surveys of mental or infectious diseases, where the data are processed for taking measures or decisions regarding specific individuals on a large scale;***	category. Research using data concerning health would be captured in 2(b), but would generally be excluded from 2(d) because data are not usually processed for taking measures or decisions regarding specific individuals on a large scale. If research is included in the high risk category, compliance with the additional regulatory requirements will have significant resource implications for research organisations. This extra layer of regulation is not necessary when research is already tightly governed and regulated under European and Member State law.	a large scale.
Data protection impact assessment			
AM 129 Article 33 (1)	***Where required pursuant to point c of Article 32a(3) ~~where processing operations present specific risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes,~~*** the controller or the processor acting on the controller's behalf shall carry out an assessment of the impact of the envisaged processing operations on the ***rights and freedoms of the data subjects, especially their right to*** protection of personal data. ***A single assessment shall be sufficient to address a set of similar processing operations that present similar risks.***	This amendment provides clarification that data protection impact assessments (where necessary) do not need to be repeated where processing operations present similar risks. This is an improvement on the Commission's proposal since it will reduce the administrative burden of compliance without additional risk to data subjects.	Support LIBE amendment 129

International transfers – * high priority			
AM 138 Article 42(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 within the Union, the supervisory authority shall apply the consistency mechanism referred to in Article 57.~~***	International research collaborations are an important component of academic and commercial scientific research and may require international transfers of personal data. The deletion of the option to seek prior authorisation as a basis for international transfers is likely to compromise the ability to transfer data to the United States and other countries outside the EU that collaborate in research.	Oppose LIBE amendment 138 and / or add a derogation for international transfers for research purposes, subject to the conditions and safeguards referred to in Article 83. For example, amendments 306 and 411 of the Industry, Research and Energy committee opinion (26 February 2013): Article 42 – paragraph 2 – point e (new) Transfers by way of appropriate safeguards ***(e) for historical, statistical or scientific purposes, the measures referred to in Article 83(4);*** Article 83 – paragraph 4 (new) Processing for historical, statistical and scientific research purposes ***A controller or processor may transfer personal data to a third country or an international organisation for historical, statistical or scientific purposes 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) the recipient does not reasonably have access to data enabling the attribution of information to an identified or identifiable data subject; and*** ***(c) contractual clauses between the controller or processor and the recipient***

			of the data prohibit re-identification of the data subject and limit processing in accordance with the conditions and safeguards laid down in this Article.
Freedom of expression			
AM 189 Article 80 (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 ***and specific data processing situations in Chapter IX whenever this is necessary*** ~~***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 ***in accordance with the Charter of Fundamental Rights of the European Union***.	This amendment enables Member States to provide exemptions for a wider range of activities to promote freedom of expression than the Commission draft. This amendment creates scope for arts and humanities research to be conducted under this exemption. This is important because some arts and humanities research, such as law and history, is not compatible with the research model set out Article 83 and would not be permitted otherwise.	Support LIBE amendment 189
Research using data concerning health – ** critical priority			
AM 191 Article 81 (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***	This amendment introduces special consent rules for the use of data concerning health in scientific research. The wording "one or more specific and similar researches" is ambiguous. This would create a lack of clarity around whether the consent used for a particular study would comply.	Oppose LIBE amendment 191

	the consent at any time.		
AM 191 Article 81 (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~~ shall be permitted only with the consent of the data subject, and shall be*** subject to the conditions and safeguards referred to in Article 83.	This amendment makes the exemption from consent for the use of data concerning health in research very narrow. This will prevent valuable health research that is currently legal and already tightly regulated under European and Member State law. While the amendment enables Member States to legislate for an exemption, the permitted exemption is very narrow: • The exemption could only apply to the use of pseudonymised, not identifiable, data. • A very high bar is set for research using pseudonymised data to be eligible for the exemption, which lacks any assessment of proportionality or reasonableness. Particular concerns include: • "High public interest" suggests the exemption is to be used only in a very limited set of circumstances. This is likely to be problematic for many studies, particularly because the results and impact of the study are not known at the outset. • "Cannot possibly be carried out otherwise" creates a strict test that does not take into account the nature of research, for example, it is not clear how one could show that a particular research project "cannot	Oppose LIBE amendment 191
AM 191 Article 81(2a)	***Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves a high public interests, 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.***		

		possibly be carried out otherwise" where it is theoretically possible, but not practicable (because of the sample size needed), to seek consent. • The requirement for pseudonymisation to be at "the highest technical standards" lacks an assessment of reasonableness. This is problematic because research resources are often used over many years. Even where a study can demonstrate "highest technical standards" when it is first established, it would be impractical to ensure compliance with this requirement every single time data are used in the future, as this would require continual updating of standards and processes. These amendments also produce an overlap between Articles 81 and 83, creating legal uncertainty. Research is an international activity and would benefit from clear and harmonised rules that facilitate research across Member States. However, Member State-based exemptions will limit the potential for harmonisation.	
AM 86 Recital 123a	***The processing of personal data concerning health, as a special category of data, may be necessary for reasons of***	The concept of "high public interest" is problematic. "High public interest" suggests the exemption is to be used only in a very	Oppose LIBE amendment 86

	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.	limited set of circumstances. This is likely to be problematic for many studies, particularly because the results and impact of the study are not known at the outset.	
Processing for historical, statistical or scientific research purposes – ** critical priority			
AM 194 Article 83(1)	***In accordance with the rules set out in 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~~ under the highest technical standards, and all necessary measures are taken to prevent unwarranted re-identification of the data subjects.***	This amendment makes the exemption from consent for the use of health data in research very narrow, which will prevent valuable research that is currently legal. The amendment only applies to the use of pseudonymised, not identifiable, data. In addition, the requirement for pseudonymisation to be at "the highest technical standards" lacks an assessment of reasonableness. This is problematic because research resources are often used over many years. Even where a study can demonstrate "highest technical standards" when it is first established, it would be impractical to ensure compliance with this requirement every single time data are used in the future, as this would require continual updating of standards and processes.	Oppose LIBE amendment 194