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Analysis: Research and the General Data Protection Regulation - 2012/0011(COD)

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INTRODUCTION

This analysis is based on the text voted on by the Council of Ministers and European Parliament in April 2016. It considers only text that is specific to research. However, there are other significant changes for data controllers across all sectors, including research, these include: the requirement to demonstrate compliance (A.5, 13 & 30); requirements for a Data Protection Officer (A.37-39); rules on data breaches (A.33 & 34); and sanctions, including fines up to €20million or 4 per cent of global turnover (A.83).

This analysis is intended to inform those developing guidance and legislation to implement the Regulation, rather than as advice for data controllers. This is a working document that we will update as discussions develop. Please contact Dr Beth Thompson with feedback.

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Key articles and recitals	Analysis and commentary	What is needed
Pseudonymisation and scope of the Regulation		
Article 4(5) 'pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person; **Recital 26** … Personal data which have undergone pseudonymisation, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person. To determine whether a natural person is identifiable, account should be taken of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly. To ascertain whether means are reasonably likely to be used to identify the natural person, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration the available technology at the time of the processing and technological developments.	The Regulation introduces a definition of "pseudonymisation" in Article 4(3b) that was not included in the 1995 Directive. Article 4(3b) does not indicate whether data that have undergone pseudonymisation should be considered personal data; this is dealt with in Recital 26. Recital 26 can be read that all pseudonymised data should be considered personal data. The concept of identifiability also appears to have been expanded compared to the Directive by the reference to "singling out". However, the scope of identifiability is qualified by the reference to "means reasonably likely to be used" as under the 1995 Directive. This suggests that there may be cases where pseudonymised data together with a combination of appropriate organisational, legal and technological measures can be considered anonymous data. A proportionate and context-dependent approach would take into account the range of measures used, including pseudonymisation, to determine whether the data is considered to be identifiable. In order to achieve this it is important to consider the text of Recital 26 in full to understand how the scope of the regulation relates to approaches commonly used in research. The definition in Article 4(3b) does not capture the critical feature of pseudonymisation, where a unique identifier is used to an distinguish individual in a dataset without revealing their real identity. This makes the definition broader than that typically used in research. However, the implications of this are unclear.	***European Data Protection Board (EDPB) or Member States:*** **To provide guidance on the interpretation of R.26 to clarify the scope of the Regulation**. This should take into account the full range of approaches used to minimise the likelihood of identification. It would be valuable for this guidance to refer specifically to the research context where pseudonymisation is used in combination with strict organisational, legal and technological measures to reduce identification risks. Further clarity on the nature of the technical and organisational measures described under 4(3b) would also be valuable, for example to understand whether additional information must always be kept separately by a different data controller, or whether this can be achieved *within* a data controller. ***UK:*** **To maintain the proportionate and context-dependent approach of the Information Commissioner's Office *Anonymisation Code of Practice*** and make updates as necessary.

Principles of data protection: further processing		
Article 5(1)(b) [Personal data shall be:] collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation'); **Recital 50** The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis separate from that which allowed the collection of the personal data is required. ... Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be considered to be compatible lawful processing operations. ... **Recital 156** … The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data) …	The Regulation prevents personal data collected for one purpose being used for another incompatible purpose. A.5(1)(b) and Recital 40 explain that further processing for scientific research, statistical or historical purposes can be considered “not incompatible” purposes. Further processing for research is therefore permitted, consistent with the 1995 Directive. Recital 40 also clarifies that not incompatible further processing can rely on the same legal basis as that used for the collection of the data . In order to benefit from this provision: - The safeguards set out in A.89 and Recital 156 must be fulfilled, including that anonymous data could not be used instead. - Where special categories of personal data – such as data concerning health – will be processed, the conditions of A.9 must also be met (see below). This provision is important because it facilitates further processing of data for research, for example by allowing routinely collected data such as hospital records to be used in studies.	***Member States:*** **To put in place clear requirements for A.89 safeguards** (see p 11)

Principles of data protection: storage		
Article 5(1)(e) [Personal data shall be:] 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 personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation');	A.5(1)(e) enables personal data to be stored for longer periods than necessary where it will only be used for archiving purposes in the public interest, or scientific research, statistical or historical purposes. This is consistent with the 1995 Directive. In order to benefit from this provision: - The safeguards set out in A.89 must be fulfilled. - Appropriate technical and organisational measures are also required to protect data subjects, but these do not appear to be in addition to those required elsewhere in the Regulation, for example A.89.	***Member States:*** **To put in place clear requirements for A.89 safeguards** (see p 11)
Lawfulness of processing		
Article 6(1) Processing shall be lawful only if and to the extent that at least one of the following applies: (a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes; (b) …; (c) …; (d) …; (e) 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; (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, 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.	Processing of personal data needs to meet one of the legal bases in A.6(1) to be lawful. It is important that it is clear which legal bases are appropriate for research to provide legal certainty for researchers and their institutions. This is more important under the Regulation where data controllers must be able to demonstrate compliance and where the legal basis for processing must be included in both a register of processing and a fair processing notice provided to data subjects. Under the 1995 Directive, Member States have taken different approaches in terms of which legal bases are preferred for research, so guidance is important to promote a more consistent approach. *Consent* A.6(1)(a) may be a practical option in some cases. Specific issues relating to consent, including the conditions that must be met, are discussed below (see	***Member States:*** **To use the flexibility in A.6(2) and (3) to create a dedicated public interest legal basis for scientific research for private and public organisations**, if such basis does not already exist that fulfils the requirements of Recital 41 and A.89(1). This will ensure there is a clear legal basis to support research. ***EDPB or Member States:*** **To provide guidance on the appropriate use of different legal bases for research,** including alternative(s) to consent.

Recital 45 Where processing is carried out in accordance with a legal obligation to which the controller is subject or where processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority, the processing should have a basis in Union or Member State law. This Regulation does not require a specific law for each individual processing. … It should also be for Union or Member State law to determine whether the controller performing a task carried out in the public interest or in the exercise of official authority should be a public authority or another natural or legal person governed by public law, or, where it is in the public interest to do so, including for health purposes such as public health and social protection and the management of health care services, by private law, such as a professional association. **Recital 47** The legitimate interests of a controller, including those of a controller to which the personal data may be disclosed, or of a third party, may provide a legal basis for processing, provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, taking into consideration the reasonable expectations of data subjects based on their relationship with the controller. ... Given that it is for the legislator to provide by law for the legal basis for public authorities to process personal data, that legal basis should not apply to the processing by public authorities in the performance of their tasks. …	page 6). However, A.9(2)(j) the Regulation recognises that consent is not always possible for the processing of personal data in research. It is therefore important that an alternative basis in A.6 is clearly available to support this. Options include: *Public interest* A.6(1)(e) To rely on this route there must be basis in Member State or Union law. This basis should determine the purpose of processing, as well as any conditions. Member States can also allow this basis to apply to private organisations where justified by the public interest (Recital 45). Scientific research increasingly involves collaboration between the public and private sectors. Therefore this may provide a useful and consistent route to legitimise research across both the private and public sectors. *Legitimate interests* A.6(1)(f) This route may be used where legitimate interests of the controller are not overridden by the interests of the data subject. Recital 38 discusses the factors that need to be considered in establishing whether or not this is a suitable legal basis, and also notes that legitimate interests cannot be used by public bodies. This is an important consideration since under the UK Data Protection Act 1998, universities are considered public authorities and would nt be able to rely on this legal basis if the same interpretation was to be used. Under the 1995 Directive, the Article 29 Working Party opinion on legitimate interests notes that scientific research is an area where legitimate interest may be a suitable legal basis. This suggests this may also be suitable legal basis for research under the regulation. However, because it is restricted to private organisations, the scope of this is limited.	

Conditions for consent		
Recital 33 It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to 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.	Recital 33 creates flexibility in the interpretation of the definition of consent in the context of scientific research. Under the 1995 Directive, consent has often been interpreted narrowly. R.33 creates an opportunity to bring consent recognised under the Regulation closer to current practice in research in some Member States, where broad consent is used where future uses of the data in research cannot be predicted. Where consent is used as the legal basis, the conditions in Article 7 will also need to be met, including: - The data controller must be able to demonstrate consent. - The request for consent for data protection must be presented in a way that is "clearly distinguishable" from any consent being sought for other matters. - Data subject must have the right to withdraw his or her consent at any time. - In addition, some data subject rights only apply where consent or legitimate interests is used as the legal basis. It is important that the inclusion of broader forms of consent in the Regulation does not undermine good research practice around broad consent, for example ensuring appropriate governance arrangements are in place.	***EDPB or Member States:*** **Guidance on the interpretation of R.33** to understand the scope of acceptable consent and supporting conditions. In particular, the final sentence of R.33 needs clarification as it will not always be practical for researchers to allow participants to consent to some parts of a project but not others. ***UK:*** In the UK there is currently a significant difference between the standards of consent required for medical research under the Data Protection Act and under common law. In implementing the Regulation and R.33, **opportunities should be explored to bring data protection and common law consent standards closer together**. This could have the benefit of simplifying the legal framework for researchers, and making consent a more practical legal basis for research in some cases.

Processing of special categories of personal data		
Article 9 1. Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade-union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited. 2. Paragraph 1 shall not apply if one of the following applies: … (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 or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3; (i) 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 or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy; or (j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.	Article 9 prohibits the processing of special categories – including data concerning health – apart from in a specified set of uses. Article 9(2)(j) enables special categories – including data concerning health – to be processed for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes, as long as the safeguards required by A.89 are met, and where the processing is based on Union or Member State law. Union or Member State law to enable this clause to be used must meet the following conditions: - be proportionate to the aim pursued; - respect the essence of the right to data protection; and - provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject. This approach is similar to the 1995 Directive, which allowed Member States to create a derogation to permit this type of processing for reasons of substantial public interest, as long as suitable safeguards are in place. Article 9(2)(h) and (i) are also available to permit the processing of special categories of data for the management of health and social care and public health, including quality and safety of medicines and devices. These provide helpful certainty that processing that falls on the boundary between research and healthcare, such as audit, are covered by the derogations. Union or Member State law may provide further alternatives in the substantial public interest (Article 9(2)(g)). Article 9(4) also Member States to introduce further conditions, including limitations, for the processing of genetic data, biometric data or data concerning health.	***Member States:*** **To put in place clear requirements for A.89 safeguards (see p 11) that also fulfil the conditions in A.9(2)(j).** ***Commission:*** **To provide guidance for Member States on how to fulfil the conditions in A.9(2)(j)**, for example “respect the essence of the right to data protection”.

Data subject rights: Information to be provided to the data subject		
Article 14(5) Paragraphs 1 to 4 shall not apply where and insofar as: … (b) the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available; …	Article 14(5)(b) provides an exemption for research from the requirement to provide information to the data subject where the data were *not* obtained directly from the data subject, consistent with the 1995 Directive. The relationship between the different conditions listed in Article 14(5)(b) needs to be clarified. However, it appears to apply where: - the provision of such information proves impossible or would involve a disproportionate effort; *and* - the conditions of A.89(1) are met *or* where applying the right would seriously compromise the purpose. In addition, the controller must take measures to protect data subject rights, including making the information publicly available. There is *no* exemption from the requirement to provide information to the data subject where the data were obtained directly from the data subject (Article 13). The information requirements have also increased significantly compared to the 1995 Directive and are listed in A.13. It is not clear whether the information requirements in Article 13 and 14 only need to be provided at the time of data collection, or after this point when any of these details change. The latter scenario may create difficulties for organisations that hold data for long periods of time, where this may be challenging to implement and incur a very high regulatory burden.	***Member States:*** **To put in place clear requirements for A.89 safeguards** (see p 11) ***EDPB or Member States:*** **To provide guidance on** **a. the conditions needed for the research exception in A.14(5)(b) to apply** **b. how the information in A.13 and A.14 should be provided in practice.** For example: - Does the information need to be provided at the time of collection, or on an ongoing basis? - How does this relate to not incompatible further processing for research under 5(1)(b)? For example, if data are originally gathered directly from a patient for direct care purposes, then would a change in purpose to research require notification under A.13 or A.14?

Data subject rights: Right to erasure ("right to be forgotten")		
Article 17(3) Paragraphs 1 and 2 shall not apply to the extent that processing is necessary: … (d) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing; or …	Article 17(3)(d) provides an exemption for research from the right to erasure. This means that data controllers will be able to continue to store personal data for research in the event of a request for erasure from a data subject, as long as: - the conditions of A.89(1) are met; *and* - applying the right would seriously compromise the purpose.	***Member States:*** **To put in place clear requirements for A.89 safeguards**
Data subject rights: Right to object		
Article 21(6) Where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Article 89(1), 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 21(6) clarifies that the right to object to the processing of personal data does generally apply to research. Data subjects can exert this right on "grounds relating to his or her particular situation". This suggests that a data subject must have a reason to object that relates to them as an individual. Article 21(6) limits any exception to the right to object for research to where the processing is necessary for a task carried out in the public interest. However, this limitation is not restricted to situations where the objection seriously compromise the purpose (unlike a number of the other research derogations). The limitation on the right to object to cases where the processing is necessary for a task carried out in the public interest, may therefore be interpreted to apply in all cases where processing is based on A.6(1)(e). A.89 also enables Member States to create derogations from the right to object for research.	***Commission:*** **To provide guidance on the relationship between A.21(6) and A.89** to provide Member States with clarity on the scope of the derogation that they are permitted to produce.

Processing of personal data and freedom of expression and information		
Article 85 1. Member States shall by law reconcile the right to the protection of personal data pursuant to this Regulation with the right to freedom of expression and information, including processing for journalistic purposes and the purposes of academic, artistic or literary expression. 2. For processing carried out for journalistic purposes or the purpose of academic artistic or literary expression, Member States shall provide for exemptions or derogations from Chapter II (principles), Chapter III (rights of the data subject), Chapter IV (controller and processor), Chapter V (transfer of personal data to third countries or international organisations), Chapter VI (independent supervisory authorities), Chapter VII (cooperation and consistency) and Chapter IX (specific data processing situations) if they are necessary to reconcile the right to the protection of personal data with the freedom of expression and information. 3. …	Article 85 enables Member States to provide derogations for academic expression. This is important for arts and humanities research, such as politics and modern history, which is unlikely to fit the research model set out in Article 89. The Member State derogations can reach across most parts of the Regulation, but must balance the right of data protection with the freedom of expression.	***Member States:*** **Pass legislation, as required, to implement A.85, which facilitates research in the arts and humanities.**

Processing for historical, statistical and scientific research purposes		
Article 89 1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner. 2. Where personal data are processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes. 3. … 4. Where processing referred to in paragraphs 2 and 3 serves at the same time another purpose, the derogations shall apply only to processing for the purposes referred to in those paragraphs.	Article 89(1) requires safeguards to be put in place for the processing of personal data for research. The following derogations and special provisions for research can only be used if these safeguards are in place: - A.5(1)(b) and (e) - further processing and storage - A.9(2)(j) - processing of special categories of data - A.14 (5)(b) - information requirements - A.17(3)(d) - right to erasure - A.21(6) - right to object Recital 156 clarifies that Member States should provide these safeguards. Article 89(1) specifies some necessary features of these safeguards: - Anonymous data should be used instead of personal data where possible. - Technical and organisational approaches must ensure the processing of personal data is limited to the minimum needed, which may include pseudonymisation of data where possible. Article 89(2) allows Union or Member States to create laws that create further derogations from the following data subject rights: - A.15 - right to subject access - A.16 - right to rectification - A.17a - right to restriction of processing - A.19 - right to object (Note there is a mismatch between those articles that can be derogated from specified in A.89(2) as listed above, and the longer list in Recital 156). These derogations can only apply where: - the conditions of A.89(1) are met; *and* - applying the right would seriously compromise the purpose; *and* - the derogations are necessary for the purpose to be achieved.	***Member States:*** **Ensure their legal framework. is sufficient to implement A.89 and facilitate scientific research:** - **Appropriate safeguards** to fulfil the conditions of A.89(1), and also A.9(2)(j) where these will be used to permit the processing of special categories of data for research. - **Creating further derogations** in national law to support research. **Passing specific legislation is likely to provide the clearest and most certain framework for researchers.** **We encourage Member States to work together to promote compatibility between national approaches where possible**, to facilitate cross-border research **UK:** - **Ensuring that safeguards for A.89(1) take into account and work with current regulatory approaches**, for example Research Ethics Committee approval, and s.251 approvals as advised by the Confidentiality Advisory Group for England and Wales.

Recital 156 The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. Those safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation. … Member States should provide for appropriate safeguards for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. …	Member States will produce their own safeguards and derogations. This flexibility enables Member States to take an approach that is socially acceptable and fits their existing regulatory and governance system for research. However, this approach will also mean that cross-border research projects will face challenges in trying to comply with different approaches.	- **Taking a joined up view** across health data and other data sources. - **Providing clear guidance** on how the new law fits with common law and other research approvals.