

22 February 2012

Proposed FEAM and Wellcome Trust amendments to EC Proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (COM(2012)0011)

Recital 40

Text from the Commission	Proposed Amendment
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.	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 such as 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.

Justification

This amendment clarifies that historical, statistical and scientific purposes are intended to be deemed 'not incompatible' purposes. While this appears to have been the intention of the original draft in order to be consistent with the 1995 Data Protection Directive, the use of "in particular" is ambiguous. This amendment is supported by the proposal to introduce a new paragraph 2 in Article 83.

**Article 14 – Paragraph 5 – point (e) (new)
Right of the data subject to information**

Text from the Commission	Proposed Amendment
Paragraphs 1 to 4 shall not apply, where: a) the data subject has already the information referred to in paragraphs 1, 2 and 3; or (b) the data are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort; or (c) the data are not collected from the data subject and recording or disclosure is expressly laid down by law; or	Paragraphs 1 to 4 shall not apply, where: (a) the data subject has already the information referred to in paragraphs 1, 2 and 3; or (b) the data are not collected from the data subject and the provision of such information proves impossible or would involve a disproportionate effort; or (c) the data are not collected from the data subject and recording or disclosure is expressly laid down by law; or

(d) the data are not collected from the data subject and the provision of such information will impair the rights and freedoms of others, as defined in Union law or Member State law in accordance with Article 21.	(d) the data are not collected from the data subject and the provision of such information will impair the rights and freedoms of others, as defined in Union law or Member State law in accordance with Article 21; <u>or (e) the data are processed for historical, statistical or scientific research purposes subject to the conditions and safeguards referred to in Article 83 and the provision of such information proves impossible or would involve a disproportionate effort.</u>
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Justification

The right of the data subject to information could be problematic for research in situations where notifying participants would create a disproportionate burden that could prevent the research from proceeding. The Regulation includes a 'disproportionate effort' provision where the data are not collected from the data subject. However, in research studies where data *are* collected from the data subject, it may not always be possible or may be prohibitively burdensome for researchers to provide information to data subjects.

**Article 83 – Paragraph 1
Processing for historical, statistical and scientific research purposes**

Text from the Commission	Proposed Amendment
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.	Within the limits of this Regulation, personal data may be processed for historical, statistical or scientific research purposes <u>under paragraph 2 of Article 6 and point (i) of Article 9(2)</u> only if: (a) these purposes cannot be otherwise fulfilled <u>reasonably be achieved</u> by processing data which does not permit or not any longer permit the identification of the data subject; <u>and</u> (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.

Justification

Article 83 establishes an independent legal basis for the processing of personal data for historical, statistical and scientific purposes, provided the criteria in Article 83(1) (a) and (b) are met. This proposed amendment clarifies that data controllers may rely on an alternative legal basis, such as consent of the data subject, for processing of personal data for historical, statistical and scientific purposes rather than relying on paragraph 1 of Article 83.

This amendment retains the safeguard that anonymised data should be used in place of personal data wherever possible. However, this amendment provides for a test based on what can reasonably be achieved, rather than the very strict test in the current draft that may prove prohibitive to research. This amendment also provides a conjunction between points (a) and (b) for clarity.

**Article 83 – Paragraph 2 (new)
Processing for historical, statistical and scientific research purposes**

Text from the Commission	Proposed Amendment
	<u>2. Further processing of data for historical, statistical or scientific research purposes shall not be considered as incompatible under point (b) of Article 5(1) provided that the processing:</u> <u>(a) is subject to the conditions and safeguards of this Article; and</u> <u>(b) complies with all other relevant legislation.</u>

Justification

This amendment clarifies that historical, statistical and scientific research purposes are intended to be not incompatible purposes, by relating Article 5(1)(b) to Article 83. The proposal would ensure that the Regulation is consistent with the previous 1995 Data Protection Directive, which states that “Further processing of data for historical, statistical or scientific purposes shall not be considered as incompatible provided that Member States provide appropriate safeguards.” (Art. 6(1)(b)). [Note: this amendment is consistent with the Council Presidency’s proposed changes in the version dated 22 June 2012.]

**For further information please contact Dr Beth Thompson, Policy Adviser, Wellcome Trust:
E: b.thompson@wellcome.ac.uk T: +44 (0) 20 7611 7303
The FEAM statement is available from: www.feam.eu.com**

FEAM – Federation of European Academies of
Medicine
Palais des Académies
Rue Ducale 1
B-1000 Brussels

www.feam.eu.com

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Wellcome Trust
Gibbs Building
215 Euston Road
London NW1 2BE
UK

www.wellcome.ac.uk

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