To the Members of the Civil Liberties Committee (LIBE) of the European Parliament

Brussels, 19 September 2013

Consent in the field of research
General Data Protection Regulation - 2012/0011(COD)
Compromise amendments on Articles 81 and 83

Dear MEP,

In the context of the negotiations on the General Data Protection Regulation in the Civil liberties Committee (LIBE), two Compromise Amendments on Articles 81.1.b) and 83.1.a) introduce that *"a **one-time consent** is sufficient for the processing of medical data exclusively for public health purposes of epidemiological, translational and clinical research."*

Ahead of the vote in the LIBE Committee, we would like to alert you that this amendment openly violates all internationally recognised standards on informed consent in medical ethics:

In practice, 'one time consent' would imply that a patient could be asked to blindly consent to the use of his or her personal data for any potential future research study, without knowing what the data will be used for, by whom, when, at what frequency, etc. This may lead to a series of undesirable results. For instance, patients might be happy to take part in one specific research study but not in another one. Hence, 'one time consent' would have the reverse effect of patients simply refusing to consent for research as a whole while they would have happily participated in some specific research projects if they were offered the choice. Also, one has to acknowledge that personal views very often change in the course of life and consent given e.g. at a young age may not be effective many years later, in case of 'one-time consent' there is no such assumption.

The principles of autonomy and self-determination are central in medical research. Every patient has the right to decide for himself, in a voluntary way and free from any undue influence. For most clinical situations, a consent is concluded by the patient coming to a physician and seeking treatment. To consciously decide on whether or not he wants to take part in a research study, the patient needs to be fully informed of the foreseen risks and benefits of the study, but also of his rights as well as possible alternatives. The ethical conduct of medical research is based on the premise that this principle is fully respected.

'Informed consent' is internationally recognised since decades in numerous texts such as the World Medical Association's Declaration of Helsinki (Article 24), the Council of Europe's Convention on Human rights and biomedicine (Article 5), the Charter of fundamental rights of the European Union

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(Article 3), as well as the UNESCO Universal Declaration on bioethics and human rights (Article 6). We fear that the introduction of this new notion of a 'one-time consent' is a way of circumventing the current ethical obligation for researchers to fully inform the patients of the research study characteristics.

Also we question the compatibility of 'one time consent' with Article 8 of the European Convention on Human Rights which stipulates that *"Everyone has the right to respect for private and family life (…)"*. This implies that confidentiality of the patient's data shall be ensured. Hence, it is very uncertain that a 'one-time consent' will guarantee the patient his fundamental right to privacy, since his data will be used for investigations he might simply not be aware of.

In conclusion, we urge you, as European legislator, to refuse the introduction of a "one-time consent" for research in the General Data Protection Regulation. By doing so, you will act in accordance with all international standards on medical ethics and in line with the rights of individuals to self-determination, data protection and privacy.

Sincerely,

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