

## POSITION PAPER ON PERSONAL DATA PROTECTION

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The European Society of Cardiology (ESC) supports the European Commission's initiative to reform the existing EU framework on personal data protection (Directive 95/46/EC) to strengthen people's rights, their ability to control their data and their capacity to exercise their rights more effectively.

However, in line with the positions of the [Alliance for Biomedical Research in Europe](#) and of the [Wellcome Trust](#) the ESC would like to express its strong disagreement with the European Parliament (EP) amendments introduced by the Civil Liberties, Justice & Home Affairs (LIBE) Committee to the provisions regarding:

- › the *definition of personal data and regulation of pseudonymous data*,
- › the *processing of personal data concerning health*,
- › the *processing for historical, statistical and scientific research purposes*,
- › and the *secondary processing of data*.

The European Commission proposal provides a balanced mechanism for protecting privacy, while allowing the regular pursuit of health & scientific research, which is exempted from the requirement for specific and explicit consent for the use and storage of personal data. This exemption is being jeopardised by the EP amendments, which – unless the research is serving a 'high public interest' - make it mandatory for researchers to obtain specific consent by data subjects for the use and/or re-use of their personal data even when anonymised and/or pseudonymised.

If applied, the European Parliament suggested provisions would penalise the pursuit of health and scientific research in Europe by imposing more administrative work, leading to higher costs and longer delays. What is worse, the work pursued through cohort studies, biobanks, disease registries will become unmanageable.

The stakes are high: health research is the key to identifying causes of disease and developing strategies for health promotion and prevention, as well as diagnosis and treatment - it helps save lives. Scientific research is also a key driver for innovation, economic growth and social well-being.

It is the moral duty of EU policymakers to seek a positive outcome for health & scientific research in the ongoing trilogue negotiations.

The ESC strongly encourages the following actions:

Amendment/Article	Regarding	Encouraged action
AM 6 REC 23	Definition of personal data and regulation of pseudonymous data	<u>Support</u> EP amendment
AM 15 REC 38	Definition of personal data and regulation of pseudonymous data	<u>Oppose</u> LIBE 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 98 ARTT 4(2) & 4(2)a;	Definition of personal data and regulation of pseudonymous data	<u>Restore</u> “means reasonably likely” test from Commission’s proposal in art 4(2). This will ensure consistency with Recital 23
AM 100 ART 6f	Definition of personal data and regulation of pseudonymous data	<u>Oppose</u> LIBE amendments to Articles 81 and 83 (amendments 86, 191 and 194), 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 86 REC 123a	Processing of personal data concerning health	<u>Oppose</u> LIBE amendment 86
AM 191 ART 81	Processing of personal data concerning health	<u>Oppose</u> LIBE amendment 191
AM 194 ART 83	Processing for historical, statistical and scientific research purposes	<u>Oppose</u> LIBE amendment 194
AM 29 REC 40	Secondary processing of data	<u>Oppose</u> LIBE amendments to Articles 81 and 83 (amendments 86, 191 and 194), 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 100 ART 6(4)	Secondary processing of data	
AM 101 ART 7(4)	Secondary processing of data	

The European Society of Cardiology (ESC) represents over 80,000 cardiology professionals across Europe and the Mediterranean. Its mission is “to reduce the burden of cardiovascular disease in Europe”.

The ESC provides an array of scientific and educational activities, such as the production and continuous updating of Clinical Practice Guidelines, the organisation of educational courses and initiatives, pan-European surveys on specific disease areas. It also organises the ESC Congress, the largest medical meeting in Europe, as well as subspecialty congresses, in conjunction with its constituent bodies. The ESC edits and publishes 9 of the world's leading journals on cardiology.

The ESC is a founding member of the Alliance for Biomedical Research in Europe and of the European Chronic Disease Alliance.