



International Society for Biological and Environmental Repositories

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Committee on Civil Liberties
Justice and Home Affairs

LIBE-secretariat@europarl.europa.eu

Committee Members:

This letter is in response to the Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as provided by the European Parliament and the Council of the European Union, (Brussels, 4 December 2012), from and on behalf of the Science Policy Committee of the International Society for Biological & Environmental Repositories (ISBER), a division of the American Society for Investigative Pathology (ASIP). The ISBER Science Policy Committee hereby endorses in full, the views and comments of its Regional Chapter, the European, Middle-Eastern and African Society for Biopreservation and Biobanking (ESBB) (attached).

ISBER is an international organization addressing the technical, legal, ethical, and managerial issues relevant to repositories of biological and environmental specimens (see www.isber.org for additional information). Although not restricted to human specimens intended for research, the great majority of ISBER members focus on providing human tissues for research, either procured for research purposes, or from residual clinical specimens obtained during the course of routine medical care. ISBER membership and expertise in the area of human tissues used for research is extensive, longstanding, ongoing, and representative of the best practices. ISBER's thought leaders in this area are worldwide. As such, we have a keen interest in this regulation and its implications for research within Europe as well as globally. We are pleased to submit for your consideration our comments and views as follows:

•We fully endorse the ESBB comments in response to the Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) as provided by the European Parliament and the Council of the European Union, (Brussels, 4 December 2012), which you will have received separately from ESBB, with the additional comments:

Although the amendments as currently written do not specifically mention biorepositories or those who utilize their resources to generate data, the impact upon these entities and the important health research they support will be profoundly negative. Of greatest concern is (1) the prohibition of genetic / health-related data processing without specific consent which renders waiver of consent and authorization invalid, (2) the requirement for explicit consent in the form of a statement confirming clear, affirmative action, making it impossible for researchers to utilize the "opt-out" mechanism, and (3) the requirement that data transfer be in full compliance with European regulation, while non-European countries are unable to anticipate European standards. We are concerned about the potential impact of these provisions and their possible impediment to the progress of global research.

It is important to recognize that many excellent regulations and high ethical standards already exist to provide privacy protections for the use of personal data in research. Additionally, the Declaration of Helsinki recognizes that situations exist when it is impossible or impractical to obtain consent for some research, as with the use of archived specimens and data. In such cases, consent may be waived by an ethics committee:

The Declaration of Helsinki revised version 2008 paragraph 25 states that "For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee."

We respectfully suggest that the regulation maintain a provision that would permit a waiver of consent under certain circumstances, and that the research community be engaged at every opportunity to ensure that scientific endeavors and global collaborations that are critical to advance medicine and public health are not adversely affected as influential decisions are made.

Thank you for the opportunity to comment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Kathryn Shea', written in a cursive style.

Katheryn Shea
ISBER President