BBMRI – Large Prospective Cohorts

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The EU Data Protection Regulation: A Barrier to Improved Health Care

Biomedical research and decades of European investments are in jeopardy with the proposed amendments outlined in the LIBE Draft Report (Rapporteur J.P. Albrecht) to the Directive on the Protection of Personal Data.

The European Union, through its FP7 funding program, has become a world leader investing in and creating research infrastructures for the establishment of large population cohorts essential for the future of biomedical research, specifically with regard to a better understanding of gene-environment influences on health. The goal is to provide open platforms for both public health and translational medicine in chronic, infectious, and rare diseases.

A number of well-established national biobanks and collaborative international efforts (e.g. BBMRI, P3G, BioSHaRE, EurocanPlatform, IRDiRC…) are supporting the collection of and access to longitudinal data and biological samples to ensure a systemic approach to the future of sustainable, universal, health care systems. This is being done after obtaining a broad informed consent from participants that allows for future uses of data to address a wide range of health-related questions, under secure privacy protection and governance. This ensures the most responsible and effective use of the data and samples.

All of this is now at grave risk with the proposed Draft. Why?

- The requirement of a "specific" informed consent for every separate research use of data/samples would destroy the legal foundations of current and future longitudinal studies and registries;
- The regulatory burden on registries/rare diseases/biobanks/public health will cripple the use of cohort data to improve the health of citizens in Europe and elsewhere;;
- The proposed definition of genetic data is incongruous with current definitions used in both the academic arena and public sector;
- The separation of genetic data from health data is inappropriate and contributes to social stigmatization; and, finally,
- The implementation of this Draft will put the quality and utility of European data at odds with globally accepted standards and best practices in biomedical research with a negative impact on international collaboration.

In short, the Draft, if adopted, will constitute a major impediment to future improvements of health care intended to be sustained by interoperable, biomedical research infrastructures. The Draft runs counter to the Principle of Proportionality, imposing major disadvantages in favor of minor, largely hypothetical concerns.

In view of these considerations, substantial revisions are necessary to the current Draft. In particular, we ask that the original article 83 with its exception for historical, statistical and scientific purposes be restored.

On behalf of the BBMRI community,

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