BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

16 June 2015 Day of Action 'Data for Health and Science'

Recommendations on the General Data Protection Regulation

ISC
Intelligence in Science

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Day of Action Recommendations

A Day of Action led by BBMRI-ERIC was organised on 16 June 2015 with the aim of alerting EU policy-makers to the harmful effects the General Data Protection Regulation could have on statistical, scientific, and historical research and healthcare if strict restrictions, including a requirement for specific consent, with only a narrow exception, in science and health research, are introduced. Participating organisations urged EU policy-makers to recognise the technical and ethical safeguards which already exist in research and to ensure that research and healthcare are not hindered by the General Data Protection Regulation. Outlined below are the Day of Action recommendations to the General Data Protection Regulation:

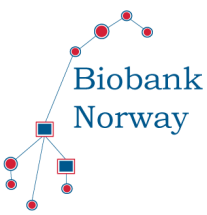
1. **The Regulation should safeguard the interests of patients in medical research.** Many patient groups say that they do not want to re-consent to each new study, having allowed the usage of their data for scientific purposes for altruistic reasons, especially those with cancer or chronic diseases. Consequently, patients should have the option to donate their data and biomaterials to biobanks and research entities without restricting their consent to a specific study. This option would allow their data to be used for biomedical research for the benefit of the donors as well as future patients. Many future research purposes are impossible to predict at the time of data collection due to constant developments and progress in science. In addition, continuous re-consent is burdensome for many patients, not least because it reminds patients of their condition. The Regulation should therefore ensure that currently available and future samples and associated data are not wasted, while protecting the data from misuse and illegal disclosure.

2. **The Regulation should maintain the distinction between use of personal data for 'historical, statistical or scientific purposes' and data processing which is potentially harmful to data subjects**. Historical, statistical and scientific research delivers benefits to society using personal data and currently protects privacy through various ethical, governance and technical safeguards. The Regulation should highlight the importance of such safeguards to protect data subjects. Existing safeguards include approval of research uses of personal data by ethics committees, legal agreements which detail appropriate use of data, pseudonymisation of personal data, and confidentiality safeguards. Institutions such as the Council of Europe and the European Group on Ethics produce codes and recommendations on how best to protect participants from potential harm resulting from participation in research. In the case of medical research, high standards of patient safety have been ensured by adherence to ethical principles set by policy instruments such as the Declaration of Helsinki, the EU Clinical Trials Regulation, and the ICH Good Clinical Practice.

3. **Harmonised rules for research at EU level would be preferable** to promote trans-national research collaboration. At the same time, the harmonised rules should not lead to a deterioration of the status quo for research. In particular, harmonised rules would be extremely valuable for rare diseases, as Pan-European studies are often necessary to

obtain sufficient data, given the small numbers of patients affected across a single country.

4. **The Council's approach, which provides derogations to Member States with respect to consent** for historical, scientific, and statistical research, **should be maintained** to avoid negative effects on research. This is particularly important for biomedical research, which is a highly controlled area with many safeguards in place to protect the confidentiality of information about patients.



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