On behalf of the e-Health Technical Committee (TC) of the IEEE Communications Society (ComSoc), we wish all our members a very instructive reading of this letter.

The contribution from this edition is coming from Nottingham Trent University and report on the current state of e-Health and EU law.

We also welcome all our members to share their research activities and field experiences through this open newsletter and to open up new opportunities for discussions and collaborations.

Dr. Nada Philip (Kingston University London, UK)
Dr. Nazim Agoulmine (University of Evry Val d’Essonne, France)

---

**Table of Contents**

1) e-Health and EU law
2) Call for papers – 41st International Engineering in Medicine and Biology Conference

---

**E-HEALTH AND EU LAW**

John Rumbold¹ and Barbara Peirscionek¹

¹Nottingham Trent University, Nottingham, UK

**I. THE GDPR AND HEALTHCARE DATA: WHAT HAS CHANGED?**

The General Data Protection Regulation (GDPR) came fully into effect in May 2018. For most of the public, the most visible effect has been countless requests for permission to keep us on a mailing list. What are the effects on eHealth?

The GDPR like all EU regulations is directly applicable. This means that EU residents can rely on its provisions without the national government passing further legislation. There are some changes relevant to the use of sensitive data. There are a greater number of changes in relation to research using sensitive data. The GDPR does lead to greater harmonisation of data protection rules, which will facilitate international research projects.

One of the purposes of the GDPR is to facilitate the Digital Single Market. The GDPR facilitates data portability by the provisions of Article 20:

The data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided.

This will benefit patients moving between healthcare providers. It will particularly aid the provision of medical services for EU nationals seeking care outside their country of
II. CONSENT

The GDPR generally requires consent to be “freely given, specific, informed and unambiguous”. This requirement would cause considerable difficulties for large-scale data research projects if the data are being re-used. Further consent is not required for scientific research on personal data, but consent is required for sensitive data (unless meeting the conditions of the relevant derogations). This consent can be for “certain areas of scientific research when in keeping with recognised ethical standards for scientific research”. In other words, broad consent but not blanket consent (1).

Consent (or the appropriate consent waiver) will be required when processing pseudonymised data. It has been clarified that pseudonymised data are categorized as personal data under the GDPR (Recital 26). This will have a significant effect on biomedical data research, as it is often important to be able to verify data or contact the data subject. Data linkage research also requires retention of identifiers or the substitution of a unique identifier.

III. PUBLIC INTEREST

An important condition for exercising the research derogation is that the research be in the public interest. The exact scope of what is in the public interest is open to interpretation. The development of a drug for commercial exploitation will be of indirect benefit to the public, but the direct public interest seems too remote. The use of healthcare data for actuarial calculations would also be for the benefit of insurance companies, rather than the wider public. Public consultations support this distinction (2,3). This also aligns with the concept of the social licence for research (4).

IV. CHANGES TO THE CATEGORIES OF SENSITIVE DATA, INCLUDING WELLNESS DATA

There has been further clarification of what comes under the category of sensitive data. Article 9 details the special categories of data that merit extra protection, and these include genetic data, data concerning health or data concerning a natural person's sex life or sexual orientation. The distinction between wellbeing and health data is not easily drawn. There is a cross-over between human behaviour and medical data in the form of “wellness data”, often produced by wearables or apps. An example is the fitness wristband that tracks activity levels. It is indubitably personal data, but could also be classified as healthcare data depending on the details recorded, how they are processed, and their use. A letter from the Article 29 Working Party defines the data from fitness trackers and wellness apps as health data if any of the following applies:

1. The data are inherently/clearly medical data
2. The data are raw sensor data that can be used in itself or in combination with other data to draw a conclusion about the actual health status or health risk of a person
3. Conclusions are drawn about a person's health status or health risk (irrespective of whether these conclusions are accurate or inaccurate, legitimate or illegitimate, or otherwise adequate or inadequate) (5)

We can see that it is not just the nature of the data, but their subsequent use, which determines whether they are health data.

V. PRIMARY USE VERSUS RESEARCH

The recent ICO investigation of the Google DeepMind/Royal Free Hospital NHS Trust project illustrates where the regulator draw
the line between audit and research. An audit process is considered part of direct patient care, as it has the potential to improve the provision of health care in that institution. However, the use of patient data to develop an app for detecting acute kidney injury does not come under that categorisation. This is considered research, and led to the censure of the Royal Free Hospital NHS Trust by the ICO (6). The amount of data processed from all patients attending the trust was excessive for audit purposes; it included patients that would have had an extremely remote risk of acute kidney injury.

These are all issues that potentially affect Big Data projects in healthcare. We have been developing the Biolytica analytics platform that can analyse different types of data in different scenarios. The major concern has been the suitable level of anonymisation. The CNIL standard of anonymisation has been used, because the anonymisation process has been carried out by a French provider, Gnubila. One of the difficulties with this is that the temporal sequence of certain events needs to be preserved.

IV. CONCLUSION

In conclusion, the GDPR has a mild effect on the conduct of biomedical research, except for the increased regulatory burden with respect to pseudonymised data.

Our work in this area is funded by the AEGLE project, Horizon2020 ICT/2014/1


[2] Ipsos MORI. The One-Way Mirror: Public attitudes to commercial access to health data. 2016.

Call for Papers

The IEEE Engineering in Medicine and Biology Society is pleased to announce the 41st International Engineering in Medicine and Biology Conference, to be held in Berlin, Germany from July 23–27, 2019. The overarching theme is “Biomedical engineering ranging from wellness to intensive care”. Consistent with our theme, we have arranged plenary keynotes from leading academic and industrial scientists, who will present aspects of innovation and translational engineering in biomedicine. The scientific tracks will cover the standard topics of the EMBS technical committees. Beside the scientific sessions, the congress exhibition will show biomedical companies, start-ups, biomedical institutes, universities, and provide networking opportunities for engineers, clinicians, other scientists, entrepreneurs and students. Cutting-edge research and innovation in biomedical engineering, healthcare technology and medical informatics will all be covered in this large conference. The conference program consists of mini symposia, workshops, invited sessions, oral and poster sessions, sessions for students and young professionals, sessions for clinicians and entrepreneurs, and a large exhibition. The conference will be held in Berlin, which is currently developing a major healthcare hub in Germany with three universities, the Berlin Institute of Health (BIH), Healthcapital, and more than 100 regional companies active in the healthcare business.

Date: July 23–27, 2019
Location: Berlin, Germany

Important Dates

Full Papers
Submission opens - August 1, 2018
Submission deadline - February 5, 2019
Accept/reject notification - April 5, 2019
Final submission deadline - April 17, 2019

1-Page Papers (Research Poster Papers)
Submission opens - August 1, 2018
Submission deadline - April 12, 2019

Themes

01. Biomedical Signal Processing
02. Biomedical Imaging and Image Processing
03. Micro/Nano-bioengineering and Cellular/Tissue Engineering & Biomaterials
04. Computational Systems, Modeling and Simulation in Medicine, Multiscale Modeling, Synthetic Biology
05. Cardiovascular and Respiratory Systems Engineering
06. Neural and Rehabilitation Engineering
07. Biomedical Sensors and Wearable Systems
08. Bio-Robotics and Biomechanics
09. Therapeutic and Diagnostic Systems and Technologies
10. Biomedical and Health Informatics
11. Biomedical Engineering Education and Society
12. Translational Engineering for Healthcare Innovation and Commercialization
13. Pharmaceutical Engineering and Drug Delivery
Accept/reject notification - April 23, 2019
Final submission deadline - April 30, 2019

**Conference Website**
https://embc.embs.org/2019/

**Systems**
14. Smart Implants