



Stakeholders Acting  
Together  
On the ethical  
impact assessment  
of Research and  
Innovation

## **Policy developments in the ethics of research and innovation**

SATORI Newsletter Issue 2:  
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### **Europe**

#### **European Medicines Agency Reports Results of Project to Improve Timely Access for Patients to New Medicines**

Between 2014 and 2016, the European Medicines Agency (EMA) ran a pilot project on the “adaptive pathways” approach to improving patient access to new medicines. The approach focuses on areas of high medical need and builds on regulatory processes already in place within the EU legal framework. In July, the EMA published a report on the project that reflects the experience gained in the pilot, discusses the practical findings and outlines the next steps. A follow-up project is planned, beginning with a workshop on 8 December 2016 to discuss the approach with stakeholders.

Sources:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000601.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2016/08/WC500211526.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/08/WC500211526.pdf)

Discussion: <http://www.euractiv.com/section/health-consumers/news/eu-drugs-agency-to-unveil-results-on-early-medicines-project-this-week/>

#### **Preparations for 2016 Brussels Declaration Towards Ethics & Principles of Science-Policy Making**

A five-year initiative on science-policy-making involving over 250 international groups and networks ended in Manchester in July 2016. The initiative resulted in a draft text with 20 principles that will form a basis for the launch of the Brussels Declaration in September 2016. The aim of the

bottom-up initiative was to foster engagement between different stakeholders who may not otherwise interact. The meeting in Manchester explored questions having to do with the relationship between science, policy and society as well as expectations of the scientific and policy-making communities.

Source:

<http://www.alphagalileo.org/ViewItem.aspx?ItemId=166472&CultureCode=en>

## **European Commission finalises the Code of conduct on privacy for mHealth apps**

The Code of Conduct on privacy for mobile health apps has been formally submitted for comments to the Article 29 Data Protection Working Party for approval. Once approved, the Code will be applied in practice, allowing app developers to voluntarily sign it, thus making a commitment to follow its rules. Those rules are based on EU data protection legislation and cover issues such as: user's consent, data subjects' rights and information requirements, security measures, use of personal data for secondary purposes and data gathered from children.

Source: <https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-been-finalised>

## **Conference on Radical Ideologies and Violent Extremism: The Role of Research**

The European Commission is organising a conference on the role of research in addressing radical ideologies and violent extremism in Brussels on 26 September 2016. The conference marks the completion of a policy review on that topic, which will be presented at the conference. One goal of the conference is to emphasize knowledge gaps and research needs in these areas at the European level.

Source:

[http://ec.europa.eu/research/conferences/2016/addressing\\_extremism/index.cfm](http://ec.europa.eu/research/conferences/2016/addressing_extremism/index.cfm)

## **Finland**

### **Finnish Defence Forces Accuse Researchers of Leaking Results of Psychological Tests**

Results from psychological tests of hundreds of thousands of conscripts have been leaked to researchers in the United Kingdom, according to Finnish Defence Forces. The Defence Forces have the power to determine which researchers are granted access to the test results, but no permission to access the data can even be granted to foreigners. Researchers are required to remove all identifying information from the data, and it is unknown whether the researchers complied with this requirement.

Sources: <http://www.helsinkitimes.fi/finland/finland-news/domestic/14142-defence-forces-accuses-researchers-of-leaking-psychological-test-results.html>  
<http://www.hs.fi/kotimaa/a1469935566397>

## France

### **The National Commission for Data Protection and Liberties (CNIL) simplifies the reporting of data processing in health research projects**

By two decisions dated 21 July 2016 but published on 14 August 2016, the French National Commission for Data Protection and Liberties (CNIL) updated a Reference Methodology simplifying the reporting of data processing in clinical trials (MR-001) and created a new Reference Methodology for the reporting of personal data collected in health research projects in which consent is not needed.

Sources:

<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033028257>

<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000033028290>

## Norway

### **New Norwegian Guidelines for Research Ethics**

Norway has issued new guidelines for research ethics, with one set of guidelines for natural sciences and technology and another for social sciences, humanities, law and theology. The new guidelines update Norway's previous version, which was issued 20 years ago. Some have expressed concern that there is no mechanism in place to ensure that researchers comply with the new guidelines. Prof. Göran Collste, Professor of Applied Ethics in Sweden and member of the SATORI project, has spoken highly of the new guidelines, suggesting that they are sufficiently universal to provide input to the SATORI guidelines for research ethics in Europe.

Sources: <http://sciencenordic.com/sending-norwegian-research-ethics-out-europe>

<https://www.etikkom.no/en/ethical-guidelines-for-research/>

## United Kingdom

### **British Association for Counselling & Psychotherapy (BACP) Presents New Ethical Framework**

The BACP has developed a new ethical framework for the counselling professions. The new framework makes a number of main changes, including: explicitly recognising the roles represented in the divisions of BACP, adjusting the ethics of autonomy and identity to take account of social diversity and updating their code of *Good practice* in order to endorse the positive contribution of the counselling professions to safeguarding vulnerable people.

Source: [http://www.bacp.co.uk/ethical\\_framework/new\\_ef.php](http://www.bacp.co.uk/ethical_framework/new_ef.php)

### **Independent Review of Research Excellence Framework (REF)**

The UK government has published an independent review of the REF, led by Lord Nicolas Stern. The REF is the method used by the government to assess the research conducted at British universities. The review identified shortcomings of the REF, such as the pressure to create “impact” may hinder the exploration of new and controversial ideas. Another shortcoming identified is that mentoring, training and peer review are undervalued by the REF.

Source:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/541338/ind-16-9-ref-stern-review.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/541338/ind-16-9-ref-stern-review.pdf)

Discussion: <http://nuffieldbioethics.org/news/2016/stern-review-uk-research-assessment/>

## Global News

### **Flaw Discovered in Software used for Thousands of Brain Imaging Studies**

Functional Magnetic Resonance Imaging (fMRI) is a widely used tool for brain imaging in cognitive neuroscience. A recent study investigated the rate of false positives from 499 healthy control subjects in the resting state using fMRI with the most common software packages. Instead of finding the anticipated 5% false positives, the authors found up to 70% in some of the software packages. These results cast doubt on studies using fMRI with these software packages, especially studies showing only weakly significant results.

Source: <http://www.pnas.org/content/113/28/7900.full>

Discussion: <https://www.newscientist.com/article/2097734-thousands-of-fmri-brain-studies-in-doubt-due-to-software-flaws/>

## India

### **New Ethical Guidelines for Biomedical Research in India**

The Indian Council of Medical Research (ICMR) is revising the 2006 Ethical Guidelines for Biomedical Research on Human Participants. The new version seeks to meet ethical challenges posed by scientific advances. The ICMR has posted the draft guidelines on its website and invites feedback from stakeholders until 15 September 2016.

Source:

[http://www.icmr.nic.in/icmrnews/draft\\_ethical/draft\\_guidelines.htm](http://www.icmr.nic.in/icmrnews/draft_ethical/draft_guidelines.htm)

Draft guidelines:

[http://www.icmr.nic.in/icmrnews/draft\\_ethical/Draft%20National%20Ethical%20Guidelines%20for%20Biomedical%20and%20Health%20Research%20Involving%20Human%20Participants,%202016.pdf](http://www.icmr.nic.in/icmrnews/draft_ethical/Draft%20National%20Ethical%20Guidelines%20for%20Biomedical%20and%20Health%20Research%20Involving%20Human%20Participants,%202016.pdf)

## Singapore

### **New Guide on Data Protection Clauses for Agreements Relating to the Processing of Personal Data**

In July 2016, the Personal Data Protection Commission Singapore issued a new guide for the processing of personal data. One main purpose of the guide is to provide sample data protection clauses that organisations purchasing services may include in their service agreements with contractors.

Source: [https://www.pdpc.gov.sg/docs/default-source/other-guides/guide-on-dp-clauses-for-agreements-related-to-processing-of-personal-data-v1-0-\(200716\).pdf?sfvrsn=3](https://www.pdpc.gov.sg/docs/default-source/other-guides/guide-on-dp-clauses-for-agreements-related-to-processing-of-personal-data-v1-0-(200716).pdf?sfvrsn=3)

## Tanzania

### **The Information and Communication Technology (ICT) Commission Advised to Include a Code of Ethics as an Important Factor for Professional Recognition**

In a speech at the National ICT profession workshop on 25 August 2016, Edwin Ngonyani, Deputy Minister for Works, Transport and

Communications, emphasised the importance of ethics for ICT professionals. He suggested that ethical skills are important for gaining the trust of, as well as clearly communicating with, those who are served by ICT professionals.

Source: <http://dailynews.co.tz/index.php/home-news/53034-ict-commission-advised-to-include-ethics-in-syllabus>

## United States

### **National Institutes of Health Proposes Policy Change to Allow Funding for Scientists to Create Animal-Human Hybrids**

The NIH has proposed lifting a moratorium on funding for research involving the creation of animal-human hybrids. The hybrids are created by introducing human stem cells into the embryos of animals. One main application of the research would be to grow healthy human organs in animals. The organs could then be transplanted into humans. The NIH has proposed steps to address ethical concerns about the research that it may fund, such as restricting the way in which embryos from non-human primates can be used and excluding research involving the breeding of animals where the introduction of human cells may contribute to the germ line. The NIH has opened an invitation for public comment, which closes on 6 September 2016.

Sources: <https://www.federalregister.gov/articles/2016/08/05/2016-18601/request-for-public-comment-on-the-proposed-changes-to-the-nih-guidelines-for-human-stem-cell>  
<https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-18601.pdf>

Discussion: <http://www.npr.org/sections/health-shots/2016/08/04/488387729/nih-plans-to-lift-ban-on-research-funds-for-part-human-part-animal-embryos>

### **Drug Enforcement Administration Rejects Petition to Reschedule Cannabis**

The US Drug Enforcement Administration (DEA) denied a petition to remove cannabis from its current Schedule 1 status, a status that categorizes the plant as having no currently accepted medical use in treatment in the US, a lack of safety for use under medical supervision, and a high potential for abuse. The DEA did acknowledge that cannabis is less dangerous than substances in other schedules and announced a policy change designed to foster research by expanding the number of DEA-registered manufacturers of cannabis.

Sources: <https://www.dea.gov/divisions/hq/2016/Letter081116.pdf>  
<https://www.dea.gov/divisions/hq/2016/hq081116.shtml>

SATORI invites suggestions for policy items to include in future issues of the newsletter. To send suggestions and feedback, please email Rowena Rodrigues ([rowena.rodrigues@trilateralresearch.com](mailto:rowena.rodrigues@trilateralresearch.com)) or visit our blog: <http://satoriproject.eu/blog/>

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