



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

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

SATORI Newsletter Issue 3:  
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Compiled by Trilateral Research Ltd. on behalf of the SATORI consortium  
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[www.satoriproject.eu](http://www.satoriproject.eu)

### **Europe**

#### **Have your say: SATORI seeks public input on its ethics assessment framework**

As many readers' will know, one main goal of the SATORI project is to harmonise ethics assessment of research and innovation (R&I) in Europe. As a step towards this goal, SATORI has produced a CEN (Comité Européen de Normalisation) Workshop Agreement (CWA). The first part of the CWA provides organisations and individual researchers a tool to help them establish and run an ethics assessment unit. The second part of the Agreement provides researchers and ethics assessors a "how to" for ethical impact assessment. SATORI invites you to review the CWA and provide feedback (until 30 November 2016).

Source: [http://cordis.europa.eu/event/rcn/147616\\_en.html](http://cordis.europa.eu/event/rcn/147616_en.html)

Provide feedback here: <http://www.normontwerpen.nen.nl/Home/Category/002>

#### **Participate! Mutual learning workshops on EU ethics assessment framework launched**

The SATORI project conducted its first dialogue event with stakeholders on 12-14 October 2016 in Milan. A variety of stakeholders attended the workshop. If you are involved in ethics assessment, and would like to participate in the forthcoming SATORI workshops, get in touch with us ASAP. Workshops are planned for Warsaw (16-17 November 2016), London (24-25 November 2016), Belgrade (24-25 November 2016) and Utrecht (28 November 2016). The workshops will be an excellent opportunity to discuss and get acquainted with the SATORI proposals for ethics assessment and ethical impact assessment!

See: <http://satoriproject.eu/events/>

#### **EMA provides open access to clinical reports for new medicines for human use authorised in the EU**

As of 20 October 2016, the European Medicines Agency (EMA) provides open access to clinical reports for new medicines for human use authorised in the European Union (EU). This means anyone will be able to directly access

thousands of pages from clinical reports submitted by pharmaceutical companies to the EMA in the context of marketing-authorisation applications. The move is expected to boost transparency (and benefit innovation), increase scientific knowledge, and potentially further inform regulatory decision making in the future.

Source:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fnews\\_and\\_events%2Fnews%2F2016%2F10%2Fnews\\_detail\\_002624.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages%2Fnews_and_events%2Fnews%2F2016%2F10%2Fnews_detail_002624.jsp&mid=WC0b01ac058004d5c1)

### **Finnish MEP: discussion on algorithmic accountability and transparency is missing from Europe's digital economy framework**

Liisa Jaakonsaari, a Finland's Socialdemokratiska Parti MEP (S&D), a member of the Internal Market and Consumer Protection (IMCO) Committee and the author of a Pilot Project on algorithmic transparency, underlines that, "A dialogue among tech companies, consumers and regulators is urgently needed not only in Europe, but globally, to ensure that algorithms are audited and that citizens' rights are safeguarded".

Source: <https://www.euractiv.com/section/digital/opinion/who-sets-the-agenda-on-algorithmic-accountability/>

### **European Commission proposes modern EU copyright rules: will they help European culture flourish and circulate?**

The EC has outlined proposals to modernise copyright rules – with three main priorities: better choice and access to content online and across borders; improving copyright rules on research, education and inclusion of disabled people; and, a fairer and sustainable marketplace for creators and the press.

Source: [http://europa.eu/rapid/press-release\\_IP-16-3010\\_en.htm](http://europa.eu/rapid/press-release_IP-16-3010_en.htm)

Critique: <https://www.ft.com/content/68222036-7e81-11e6-bc52-0c7211ef3198>

## **Germany**

### **The Federal Ministry of Education and Research puts funding behind citizens' science**

For the first time, the German Federal Ministry of Education and Research (BMBF) is specifically promoting research projects involving a large number of citizens. Citizens' science provides detailed and comprehensive information from citizens, giving relevance and usefulness to scientific results. The aim of the funding is to strengthen the direct exchange between citizens and researchers, to enable new scientific questions, and to further enhance the citizens' science.

Source: <https://www.bmbf.de/de/gemeinsam-wissen-schaffen-3240.html>

## **Steps taken for the further integration of European research initiatives**

On 10 October 2016, the BMBF (the German Federal Ministry of Education and Research) launched a debate with over 600 international participants on the future of Europe's scientific cooperation. The results of the debate will form the basis for Germany's position on the future of the European Research Area (Forshungsraum) and the alignment of the successor program to Horizon 2020. A central theme was the digitisation of science under "open science" where the Ministry launched an Open-Access-Strategy to facilitate the exchange of scientific data and results.

Source: <https://www.bmbf.de/de/in-der-forschung-waechst-europa-weiter-zusammen-3416.html>

## **Hungary**

### **European Commission presents policy recommendations to enhance research and innovation in Hungary**

In response to a request by Hungary under the Policy Support Facility (PSF), the EC has prepared a report intended to improve the country's innovation performance. The peer review took place between February and July 2016, including a panel of independent experts and senior government officials from various member states. The report contains recommendations, such as, an increased role of stakeholders in overseeing national research operations and the development of a business environment that stimulates innovation.

Source: <http://ec.europa.eu/research/index.cfm?pg=newsalert&year=2016&na=na-200916>

## **Ireland**

### **President Higgins of Ireland: need for new ethical thought on socially important matters**

'When Ideas Matter: Speeches for an Ethical Republic' is a series of speeches by Irish President Michael D. Higgins. Topics covered include: challenges for human rights, women's equality, renewal of democracy etc. In this book, President Higgins underlines the importance of the "ethical connection between politics, the economy and society". In a news interview, President Higgins suggests that ethics "is about more than making sure you're not caught". Higgins' "ethics initiatives" try to point at the differences between protocols and actual awareness of the values that shape our societies.

Source: <http://www.independent.ie/irish-news/these-are-not-wild-bolshevik-values-they-are-values-for-decent-living-president-35055929.html>

## Italy

### **Responsible Research and Innovation (RRI) in the Italian R&I strategy**

The National Research Program (PNR) of the Italian Ministry for Education and Research, published earlier this year, includes, for the first time, an explicit reference to the RRI approach. The PNR document sets the strategy for funding of cooperative research and innovation actions in the next four years in Italy. Amongst the six priority areas is public-private cooperation and industrial research. This priority includes an action line on RRI aiming to strengthen coordination and synergy amongst stakeholders to promote RRI at national level and increase cooperation with the EU on the matter. The action line envisages the development of a roadmap for RRI at the national level, and guidelines for the assessment of ethical and social issues in research and innovation processes.

Source: <https://www.researchitaly.it/en/understanding/project-and-success-stories/main-projects/the-2-5-billion-national-research-programme-presented-at-miur/#null>

### **Guidance on the application of ISO 26000 in Italy**

The Ente Italiano Normazione (UNI), the Italian national standards body, and the Sodalitas Foundation recently published guidance for the application of UNI ISO 26000 - Social responsibility in organizations. The guidance is designed to address the most critical issues in the application of ISO 26000, that emerged from a consultation with companies using the standard, five years after its publication in Italy. The guidance includes operative actions and practical examples on the use of ISO 26000, with a focus on three main areas: Materiality analysis (identification of key material aspects covering economic, environmental and social impacts of the organisation); accountability and communication of sustainability performances to stakeholders; and, practicing and measuring stakeholders' engagement.

Source: [http://uni.com/index.php?option=com\\_content&view=article&id=4909%3Aindirizzi-applicativi-per-l-implementazione-della-uni-iso-26000-pubblicata-la-nuova-uni-pdr-18-2016&catid=171&Itemid=2612](http://uni.com/index.php?option=com_content&view=article&id=4909%3Aindirizzi-applicativi-per-l-implementazione-della-uni-iso-26000-pubblicata-la-nuova-uni-pdr-18-2016&catid=171&Itemid=2612)

## Netherlands

### **KNAW recommends installation of review boards to address ethical and legal dilemmas in informatics research**

The Royal Netherlands Academy of Arts and Sciences (KNAW) has [recommended the installation of ethical review boards for informatics research, based on experience gained in the field of medicine, as it believes subjects as computer](#)

[system security and software reliability often raises legal and ethical dilemmas, for example concerning the right to privacy or intellectual property rights.](#)

Report: <http://knew.nl/shared/resources/actueel/publicaties/pdf/20160919-eng-advisory-ethische-en-juridische-aspecten-van-informaticaonderzoek-web>

### **Important change in the Dutch organ donation system: from opt-in to opt-out**

The Dutch legislature has passed a bill on organ donation that changes the system from being based on an “opt-in” principle (people would have to apply to become organ donor) to being based on an “opt-out” principle (people would have to apply to *not* be an organ donor). While seen as “great news for everyone on the waiting list”, issues of ethical concern to individual autonomy persist.

Source: <http://time.com/4490016/netherlands-organ-donation-bill/>

### **From cloned hamburgers to cloned human meat? The “Yuck” factor in ethics**

The Maastricht University was the earliest to experiment with the creation of “in vitro” meat for making hamburgers from cloned animal meat. In this post, John Loike discusses the slippery slope that goes from this development towards the extreme case of cloning human meat. He argues that the ill-defined “yuck” factor eventually can guide our ethical decision making in these cases.

Source: <https://blogs.scientificamerican.com/guest-blog/making-human-hamburgers-bioethics-and-the-yuck-factor/>

## **Slovenia**

### **The Slovenian Women in Science Commission has issued its Work Program for 2016-2017**

The Slovenian Women in Science Commission has issued its Work Program for 2016-2017 addressing topics such as: ethics in research (focusing on, e.g., participation in the public debate on the Guidelines for Ethics in Science, promotion of the institutionalised treatment of ethical issues in science, eliminating bad practices, preparation of indicators for monitoring the implementation of the principles of ethics in research organizations etc.), gender equality in scientific research (through, e.g. systematic identification and monitoring of resources and gender discrimination in science), the principle of equal opportunities in strategic documents in the field of science, and international cooperation (via, e.g. Participation in the Helsinki Group, the ENRIO network and Horizon 2020).

Source (Slovenian):

[http://www.mizs.gov.si/si/delovna\\_podrocja/direktorat\\_za\\_znanost/sektor\\_za\\_znanost/dejavnost/komisija\\_za\\_zenske\\_v\\_znanosti/predstavitev/predstavitev/](http://www.mizs.gov.si/si/delovna_podrocja/direktorat_za_znanost/sektor_za_znanost/dejavnost/komisija_za_zenske_v_znanosti/predstavitev/predstavitev/)

## Switzerland

### **“Patients should have a say in clinical trials” says Annette Magrin from the Swiss Clinical Trial Organization (SCTO)**

In response to the view that clinical trials with medicine on patients often only focus on the aims of the scientists and doctors, Annette Magrin from the SCTO underlines the importance of the patient’s role in these trials and the state-of-affairs in Switzerland. By means of the European Patients’ Academy ([EUPATI](#)) project, by which means the patients and the doctors are to have an equal say on the way trials are to be conducted, Switzerland is moving towards implementing a patient-oriented clinical trials project. Although only in its infancy, the project aims to bring in new factors to the clinical trials that are relevant to the patient, and not the scientist and doctor alone.

Source: <http://www.bernerzeitung.ch/magazin/patienten-sollten-bei-studien-mitreden/story/19207585>

### **The National Advisory Commission on Biomedical Ethics criticises inconsistent regulation on genome interventions**

A new method of genetic engineering, CRISPR/Cas9, allows precise manipulation of the genotype - even in embryos. The National Advisory Commission on Biomedical Ethics has summarised the opportunities and risks of such interventions, and notes that research on embryos in Switzerland is not coherently regulated.

Source: <http://www.nzz.ch/wissenschaft/medizin/forschung-an-embryonen-ethikkommission-bemaengelt-inkohaerente-regelung-ld.92337>

Report: [http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/NEK\\_Gene\\_editing\\_Papier\\_web\\_DEF.pdf](http://www.nek-cne.ch/fileadmin/nek-cne-dateien/Themen/Stellungnahmen/NEK_Gene_editing_Papier_web_DEF.pdf)

## United Kingdom

### **Ethics officers found to have no impact on procedure for ethics approval in health research**

A recent study published in *BMJ Open* by Mary Dixon-Woods and colleagues investigated the impact of ethics officers on the evaluation of research proposals by research ethics committees (RECs) in the UK. The researchers found that intervention by an ethics officer did not increase the proportion of applications that received approval on first review. They also found that ethics officers did not reduce the amount of time needed for RECs to reach a decision.

Source: <http://bmjopen.bmj.com/content/6/8/e011973.full>

## **Designing robots or applying robotic systems? Check out BS 8611:2016!**

BS 8611: 2016, issued by the British Standards Institute (BSI) provides guidelines to identify potential ethical harm and significant ethical hazards for various robot applications. The standard provides additional guidelines to eliminate or reduce the risks associated with these ethical hazards to an acceptable level. These cover safe design, protective measures and information for the design and application of robots in various sectors such as industrial, personal care and medical.

Source: <http://shop.bsigroup.com/ProductDetail?pid=000000000030320089>

## **Global News**

### **Institute of Electrical and Electronics Engineers (IEEE) launches a new project aiming to directly address ethics during design process**

The Institute of Electrical and Electronics Engineers (IEEE), which is the largest professional association of technical professionals, has launched a new project on ethics in system design. The new standards project, IEEE P7000, will “define a process model by which engineers and technologists can address ethical consideration throughout the various stages of system initiation, analysis and design”.

Source: [http://standards.ieee.org/news/2016/ieee\\_p7000.html](http://standards.ieee.org/news/2016/ieee_p7000.html)

## **United States**

### **Alaskan Professional Teaching Practices Commission proposes changes to Code of Ethics to protect transgender students**

The Alaskan Professional Teaching Practices Commission has invited the public to submit written comments on proposed changes to the Code of Ethics of the Education Profession and related definitions. The list of proposed changes includes the inclusion of gender identification to the list of protected classes of students and classes of colleagues.

Notice of proposed changes:

<https://education.alaska.gov/ptpc/pdf/NoticeofProposedChanges.pdf>

Complete text of proposed changes: <https://education.alaska.gov/ptpc/>

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/>

## The SATORI consortium:

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