Emerging technologies and the law—organs-on-chips

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Commercial analysis: Organs-on-chips has been named as one of the top ten emerging technologies of 2016 by the World Economic Forum, but use of the technology raises questions surrounding privacy, data protection, ownership and criminal exploitation. Dr Subhajit Basu, associate professor in information technology law and deputy director of the Law and Emerging Technologies Research Group at the University of Leeds, considers the issues.

What are organs-on-chips?

Organs-on-chips (OoC) are micro-engineered systems with microfluidic channels lined with living human cells to simulate or replicate biological processes of the real organ in vitro. The main objectives and advantages of the technology include that:

- they represent a viable alternative to animal testing
- they are generally intended to be used to test new drugs, understand how the body responds to toxins and understand diseases with a view to developing better and more effective drugs
- they are likely to be more effective for drug testing and predicting human response given that actual human cells are used
- personalised chips can be developed to predict a specific individual's drug response using cells from that individual—OoC can therefore deliver personalised and precision medicine and improve the predictive power of preclinical studies
- OoC technology could ultimately lead to building a human-on-a-chip which will simulate the entire biological process in the body using different OoC. Wyss Research Institute, for instance, proposes to build a human-on-a-chip using ten OoC to understand how different organs interact with particular drugs or toxins. By linking chips together, researchers can study how reactions in one organ affect another

What are the key legal challenges associated with the use of OoC?

There are legal challenges surrounding:

- the procurement, storage and subsequent use of cells—eg what rules guide the ethical collection of cells in biomedical research?
- consent—what rules guide consent when cells are donated for research?
- privacy and data protection—are there any concerns about privacy and data protection? What measures are in place to protect the privacy of donors?
- property rights—can OoC raise questions about ownership or proprietary rights in donor cells?
- criminal and unethical use—can OoC be used for unethical or criminal purposes?

What is the most relevant current legal framework?

There is no EU-wide law or regulation in this area, despite efforts by the Tiss.EU project to harmonise EU law in this area (see Katharina Beier et al, ‘The Ethical and Legal Regulation of Human Tissue and Biobank Research in Europe’). Currently, national laws deal with the use of human tissue in research in different ways.
In the UK, the main legislation is the Human Tissue Act 2004 (HTA 2004), but HTA 2004 only deals with some of the questions raised above. For example, it regulates procurement, ethical approvals and consent.

Authorisation, licensing and ethical approvals

HTA 2004, ss 13–26 establish the Human Tissue Authority and deal with the requirement and procedure for obtaining the informed consent of donors. The functions of the Human Tissue Authority include licensing, suspension and revocation of licensing and authority to issues code of practice.

In spite of the provisions of the law on ethics, it is important to note that mass production of OoC would require large quantities of human cells. It is therefore relevant to consider how regulation can be used to ensure that cells continue to be sourced legally and ethically.

Consent

Under HTA 2004, Sch1, Pt 1, use of human tissue for research in connection with disorders, or the functioning of the human body is lawful if done with the ‘appropriate consent’. Appropriate consent means, in the case of a child, the consent of the person who has parental responsibility for the child and in the case of an adult, the consent of the adult.

Consent is not required to be in writing unless the activity falls under the categories listed in HTA 2004, ss 2(4) and 3(3). Consent is also general and not specific to purpose or use, therefore no consent is required for subsequent use of human cells in research. The law also allows for revocation and withdrawal of consent. However, while requiring consent for every subsequent use of donor cells may be onerous and detrimental to research, cells collected for one purpose and used in OoC may be subject to controversy. (This has obvious overlaps with the principle relating to the purpose and use of data under the Data Protection Act 1998. For specific cases, see the US cases of Moore v Regents of University of California, 793 P.2d 497 (Cal. 1990); Adams v King County, 192 P. 3d 891 (Wa. 2008)).

What are the grey areas?

Privacy and data protection

There is need to clarify rules on privacy and data protection. For example, it is important to protect identity because of risks of profiling and racial discrimination, particularly since OoC can be personalised for individual inquiry.

OoC will require an assessment of these risks to determine the level of protection required. However, coding, anonymisation and pseudonymisation are options which must be balanced against the need for re-identification in cases of specific research, tracing of infectious diseases etc.

Property rights

Who owns property in the organs or cells? For example, can donors, bio-banks, or researchers claim a share in the profits of any commercialisation of research results, eg licensing of patent and commercialisation of OoC
tests? (See, for example, Greenberg v Miami Children’s Research Hospital Institute 264 F.Suppl. 2d, 1064 (SD Fl. 2003)).

Criminal and unethical uses and threats to national security

Although the primary objective of the technology is to investigate toxic and therapeutic effects of drugs with a view to developing new drugs and predicting the reaction of human organs and body to new drugs, the research also creates a dilemma. On the one hand, because OoC can be used to test the toxicity of harmful chemicals, it can also be used to develop biological or chemical weapons. On the other hand, OoC can be used to develop vaccine and drugs to counter bio-terrorism threats. The questions are therefore, how can law and regulation reconcile the benefits and threats? What measures need to be put in place to ensure that OoC are not used to develop harmful chemicals for biological warfare? How can regulation be used to ensure that the technology does not fall into the wrong hands?

What is needed in terms of a regulatory response?

A uniform approach to regulation is needed at EU level, with a comprehensive law regulating the use of human tissue and cells for research (especially with Brexit in view). Directive 2001/20/EC and Directive 2005/28/EC are examples of similar EU Directives regulating clinical trials and the use of human tissue and cells used in human application.

Interviewed by Jenny Rayner.

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