

# Dynamic consent in the digital age of biology

Richman Wee LLM

The concept of ‘dynamic consent’, formulated more than a decade ago and increasingly used in a number of health information and communications technology (ICT) initiatives, has been attracting strong interest from innovators and commentators. Dynamic consent has been explored and discussed in the literature on research ethics, biobanking and genomic medicine. Early references to dynamic consent can be traced back to 2001, when stronger safeguards for protecting the confidentiality of individual medical and genetic information were being investigated, in order to support advances in the field of pharmacogenetics and personalised medicine. At that time, a rough draft of the human genome had been published by both the publicly funded international consortium, known as the Human Genome Project, and the private commercial company called Celera Genomics, headed by J Craig Venter. Last year, Venter heralded the arrival of the ‘digital age of biology’.<sup>1,2</sup> He spoke on the interchangeability of the digital and biological worlds, and envisioned a time when our personal biology would be transmitted across the internet at the speed of light.

This is the first article in a two-part series examining a selected number of overseas projects that have developed the idea of dynamic consent for use in the management of information and samples in the health context.

## Projects and collaborations exploring dynamic consent mechanisms

### First Genetic Trust

Early references to the dynamic consent approach can be traced back to 2001 when an online pro-

prietary genetic banking system was proposed by First Genetic Trust (FGT).<sup>3</sup> The concern people might have over the security of their personal genetic data was identified by FGT as a potential barrier in the development of pharmacogenetics and personalised medicine. To provide greater assurance for individuals that their privacy will be strongly protected, FGT proposed a dynamic informed consent mechanism that would protect ‘the confidentiality of individual medical and genetic information, *allowing access* to select information and the use or application of an individual’s DNA *only when* the patient has given specific consent [emphasis added].’<sup>4</sup> FGT would have the role of a third-party broker of genetic information—as an intermediary between patients or research participants on one hand, and those conducting genetic research, such as medical researchers, health care providers and pharmaceutical companies on the other hand.<sup>5</sup>

As a trusted third party, FGT would create the confidential database to the standard of ‘a structure with Swiss bank-grade security’.<sup>6,7</sup> Individuals would consent to their genetic information being stored in FGT’s database for clinical research use and they would control access to their own data. Such a protected environment would safeguard their privacy and maintain the confidentiality of their genetic and medical information while they participate in genetic research.<sup>8,9</sup> The internet would be used by FGT to maintain ongoing communication with them, for instance, to provide updates on research findings, seek consent for follow-up medical treatment or research studies, supply further detailed information about the risks and benefits of research projects, obtain specific consent for new uses of the data,

Faculty of Law—Law Foundation-sponsored Centre for Law and Policy in Emerging Technologies, University of Otago, Dunedin, New Zealand

J PRIM HEALTH CARE 2013;5(3):259–261.

The **ETHICS** column explores issues around practising ethically in primary health care and aims to encourage thoughtfulness about ethical dilemmas that we may face.

**THIS ISSUE:** This article is the first in a two-part series looking at international projects involved in the development of dynamic consent processes for accessing patient health information and samples.

### CORRESPONDENCE TO:

**Richman Wee**  
Faculty of Law,  
University of Otago,  
PO Box 56, Dunedin  
9054, New Zealand  
richman.wee@otago.ac.nz

and to re-contact them with new requests.<sup>10</sup> For researchers, FGT's internet-based systems would assist them in efficiently collecting, storing, managing and analysing the genetic and medical data for use in clinical trials.<sup>11</sup> For drug companies, the FGT database could establish the link between their company and physician networks, to enable direct access to many thousands of clinical trial patients or samples for pharmacogenetics programmes.<sup>9</sup>

### Private Access

Private Access Inc., founded in 2006 and headquartered in California, has been a widely publicised example of technology being employed for connecting a wide range of stakeholders online to generate greater awareness and participation for clinical trials, as well as to bolster recruitment, increase enrolment, and enable consent to be sought and obtained on an ongoing and interactive basis. All this is achieved with the development of an online clinical trial community that involves patients, physicians and researchers, and is used industry-wide and includes a wide range of partners, such as clinical trial sponsors, patient advocacy groups, technology providers, and other key public and private stakeholders.<sup>12</sup> In addition, Private Access provides opportunities for engaging in social networking on the clinical trial experience. Private Access extends the current capabilities of internet-based search engines, to create the ability for properly authenticated persons (for example, doctors, family members, researchers and others) to search for highly confidential or sensitive personal information, based on the 'private access' rights that each individual can create to control who can (or cannot) see all or any particular parts of the individual's information.<sup>13,14,15</sup>

The patented technology employed by Private Access offers individuals the ability to exercise dynamic, granular data control over their information. The controls are dynamic in the sense that individuals can, at any time, change previously selected preferences as their circumstances change, different needs arise, or deeper levels of trust are established. The controls provide the ability to be granular down to the desired data element, enabling individuals to

decide whether their genetic, mental health, or any other information they deem sensitive, should be shared and, if so, with whom. In addition, the Private Access online system enables the information of individuals to be searchable by selected researchers.

### EnCoRe—Ensuring Consent and Revocation

EnCoRe is a recent information and communications technology (ICT) research project that examines the design and development of dynamic consent mechanisms.<sup>16,17</sup> EnCoRe officially began in June 2008 with £3.6 million funding. The EnCoRe project, undertaken by a group of UK multidisciplinary academic researchers and industry partners, envisions giving individuals more control over their personal information. With technological 'know-how', EnCoRe aims to enable individuals to exercise the choice of granting and revoking consent over the use of their information in a way that—in the words of the researchers—would be as easy, intuitive and reliable as turning a tap on or off. The EnCoRe system has been described as a '*patient-centric* IT system which uses a "dynamic consent" approach [emphasis added].'<sup>18</sup>

Biobanking is one of EnCoRe's areas of focus for designing a system that manages consent and revocation. 'Biobanking patients', as the EnCoRe documents describe them, would achieve levels of control over how information and data relating to them are used by researchers and clinicians in two ways. The first involves methods that inform biobanking patients as to the uses of their personal information; that is, these are predominantly, if not exclusively, *informational* in nature. The second involves methods that permit them to make meaningful decisions that can affect future uses of their information; that is, these facilitate a two-way exchange of information and allow *decisional* functions to be exercised.

The key features of EnCoRe, as summarised by the researchers working on the project, can be categorised in the following four ways. First, individuals can, through the IT interface, specify their preferences about the choices they are

given about the use of their data and samples for research. Second, the EnCoRe system allows individuals to change their mind and preferences over time, and to have their choices revoked where appropriate. Third, individuals have the ability to track and audit any changes they make. Fourth, they can choose when and how they are contacted. With the EnCoRe model, consent is 'not a mere communication exercise but a bidirectional, ongoing, interactive process between patients and researchers'.<sup>18</sup>

Dynamic consent has the potential to build on key elements of informed consent and help foster deep respect for the rights and interests of patients and participants. This will be discussed further in next issue's article.

### To be continued

The second article in this series will examine two online initiatives, 23andMe and PatientsLikeMe, that utilise a system of dynamic consent for the collection and use of large volumes of health and medical data. A description of the characteristics essential to the new and evolving concept of dynamic consent will be offered. New possibilities that may be generated, as well as the limitations, will be noted. Of particular interest for the New Zealand context is the question of how dynamic consent would fit in with the local regulatory framework for informed consent.

### References

1. Venter JC. What is Life? A 21st Century Perspective. On the 70th Anniversary of Schroedinger's Lecture at Trinity College. 12 July 2012; [cited 2013 Feb 28]. Available from: <http://edge.org/conversation/what-is-life>
2. Ahlstrom Dick. Science Editor, IrishTimes.com. Leading geneticist heralds digital age of biology. 13 Jul 2012; [cited 2013 July 17]. Available from: <http://news-beacon-ireland.info/?p=5977>
3. Editor, eyeforpharma. First Genetic Trust signs agreement with Sloan-Kettering. 18 Jan 2001; [cited 2012 Sept 14]. Available from: <http://social.eyeforpharma.com/print/55106>
4. Hewlett-Packard (HP) Co. Newsroom. First Genetic Trust selects HP as technology partner. 11 Feb 2002; [cited 2012 Sept 14]. Available from: <http://www.hp.com/hpinfo/newsroom/press/2002/020211a.html>
5. Business Wire. First Genetic Trust to provide IT system to support prolonged QT research at Vanderbilt University Medical Center. 17 Jan 2005; [cited 2012 Sept 15]. Available from: <http://www.businesswire.com/news/home/20050117005478/en/Genetic-Trust-Provide-System-Support-Prolonged-QT>
6. Marshall E. Company plans to bank human DNA profiles. Science. 2001;291(5504):575.
7. Cambridge Healthtech Institute. The art of translating genomic data into clinical practice: an interview with David Wang of First Genetic Trust. Molecular Med Monthly. 2004; 41; [cited 2012 Oct 17]. Available from: [http://www.chidb.com/newsarticles/issue41\\_1.asp](http://www.chidb.com/newsarticles/issue41_1.asp)
8. iBIO News. Congratulations to First Genetic Trust for receiving banking system patent. 3 Feb 2004; [cited 2012 Oct 14]. Available from: [http://www.ibio.org/NEWS\\_EVENTS/nws-detail.lasso?nws\\_id=1232](http://www.ibio.org/NEWS_EVENTS/nws-detail.lasso?nws_id=1232)
9. Lewis G. Tissue collection and the pharmaceutical industry. In: Genetic databases: socio-ethical issues in the collection and use of DNA. Tutton R & Corrigan O, editors. Routledge: London; 2004. p 189.
10. Weir RF, Olick RS. The stored tissue issue: biomedical research, ethics and law in the era of genomic medicine. Oxford University Press; 2004. p 65.
11. GenomeWeb LLC. Hewlett-Packard Secures IT Infrastructure Partnership with First Genetic Trust, 2001; [cited 2012 Sept 14]. Available from: Bioinform. [http://h20426.www2.hp.com/products/workstation/kr/ko/fyi\\_newsletter/0305/file/BioinformFGT\\_success-story.pdf](http://h20426.www2.hp.com/products/workstation/kr/ko/fyi_newsletter/0305/file/BioinformFGT_success-story.pdf)
12. Business Wire. Pfizer and Private Access announce plans to develop online community to accelerate clinical research. 19 Aug 2009; [cited 2013 Jan 7]. Available from: <http://www.businesswire.com/news/home/20090819005806/en/Pfizer-Private-Access-Announce-Plans-Develop-Online>
13. Private Access website; [cited 2012 Sept 14]. <http://www.privateaccess.com>
14. Terry SF, Horn EJ, Scott J, Terry PF. Genetic Alliance Registry and Biobank: a novel disease advocacy-drive research solution; [cited 2012 Sept 14]. Available from: <http://pxe.org/genetic-alliance-registry-and-biobank-novel-research-solution>
15. Olsen L, Saunders RS, McGinnis JM. Patients charting the course: citizen engagement in the learning health system. Workshop summary. Washington D.C: The National Academies Press; 2011. p 99.
16. Kaye J. Ensuring Consent and Revocation (EnCoRe); [cited 2012 Dec 5]. Available from: <http://www.publichealth.ox.ac.uk/ethox/research/research-archive/ensuring-consent-and-revocation-encore>
17. EnCoRe Press Archive; [cited 2012 Dec 5]. Available from: <http://www.encore-project.info/press.html>
18. Kaye J, Whitley EA, Kanellopoulou NK, Creese S, Hughes KJ, Lund D. Rapid response to: Broad consent is informed consent. BMJ. 2011;343:d6900

### COMPETING INTERESTS

None declared.