This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

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Nuffield Council on Bioethics: *Emerging biotechnologies*
Response from HeLEX, Centre for Health, Law and Emerging Technologies; University of Oxford

HeLEX specialises in investigating the relationships between law, ethics, practice and governance in the area of emerging technologies in health. Our main research focus is on genomics and genetics, with developing interests in other disciplines including synthetic biology, nanomedicine, and stem cell research. Research at HeLEX aims to increase understanding of how the use and impact of innovative technologies in health can be accommodated within existing legal and governance frameworks, and the extent to which such frameworks may need to evolve. Current research focuses on genomics with an emphasis on biobanks, privacy, data-sharing frameworks, global governance and translational research.

Given the nature of our research, we have responded only to some of the questions posed by the consultation document.

3 What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

Genomic research is developing rapidly, aided by the relentless advancements in DNA sequencing technology. It is anticipated that the improvements in 'next generation' sequencing techniques will result in the routine use of genome-wide scans – and soon whole genome sequences – in biomedical research within the next few years. This research, and its eventual application in the field of genomic medicine – an emerging biotechnology mentioned by the Nuffield Council in this consultation – raises a number of legal and ethical problems. We are particularly interested in such issues where they concern individuals' interactions with these technologies in the research and healthcare settings.

Legally, the main issues that arise in this field will be rooted in the disciplines of information law and privacy law; the former via data protection, freedom of information, and confidentiality; the latter via a combination of human rights and the English common law. Current legal provisions set general standards for, amongst other matters, the security of data processing activities, which is entirely understandable in the case of genomic information that relates to health issues. Other provisions, which are perhaps more problematic to understand, let alone enforce, concern the degree to which individuals should be informed about the use of sensitive data in research and healthcare contexts.

Even less clear are the legal bases which relate to individuals' access to and control over these types of information in both contexts.[1] Reform of data protection laws is currently underway in Europe,[2] and the regulation of medical research may soon be overhauled with the creation of a health research regulatory agency in the UK.[3]

These steps are necessary, in our view, however it is far from clear what the resulting laws will look like, and how they will work in practice. It is hoped that a combination of soon-to-be amended data protection legislation, evolving privacy laws (for celebrities and non-celebrities alike), and, perhaps, entirely new legislation to regulate the use of health data in research will improve matters. This will take a number of years to come into effect: a fact that should not be lost sight of by those considering the interplay between ethics and the law. As things stand the law is far from clear in terms of the rights afforded to individuals whose sensitive personal data – which will include genomic data – are used in research and healthcare. We do not consider this to be an acceptable state of affairs in 2011: the law should play a more proactive role in making systems more transparent before they become more widespread. In our view, the uncertainty of the legal situation does not assist the ethical input into the regulatory debates. In terms of significant ethical challenges for genomics researchers, we would point to the accidental identification of genetic factors that reveal information that could be important to participant's health.

One of the difficulties is that genomic research results are open to interpretation, both in terms of the clinical and statistical significance, particularly for new findings. There may be a legal duty to feed back information, if a duty of care can be established, but currently we have no cases in this area that determine the scope of the duty of care for epidemiologists and secondary researchers.

There appears to be a consensus in the literature that in the case of a serious condition, where the risk is significant and treatment is available, researchers or research teams may have a moral obligation to feed this

[1] Curren, L, Kaye, J., 2010 'Revoking consent: a 'blind spot' in data protection law?' Computer Law & Security Review 26(3): 273-
283

[2] European Commission sets out strategy to strengthen EU data protection rules (IP/10/1462) 4 November 2010 (see http://ec.europa.eu/justice/index_en.htm for more details)

[3] See UK Government 'Plan for Growth' (23 March 2011) available at http://www.hmtreasury.gov.uk/ukecon_growth_index.htm

information back to research participants. However, there is greater debate about whether to feed back incidental findings where less serious conditions are identified (for instance, ones that are not life threatening), or where no treatment is available. In these cases, the potential benefits for participants of being informed need to be balanced against the participant's right not to know. This task appears to rest currently with the researcher and their team and in all likelihood decisions such as those to feedback information will be discussed with, or approved by, ethics committees. There is also uncertainty as to who should be responsible for the feedback of results and how this should be done.

In 2009, HeLEX prepared a report for theWellcome Trust on the ethical, legal and social issues arising from the use of genome wide association studies in medical research. This report is freely available on our website,[4] and discusses the issues raise above, and others, in more detail. It also contains a detailed literature review, which the Nuffield Council may find useful.

6 Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

Genomics research requires detailed, well-characterised information, such as good quality data on diseases and traits of interest. This need for large, diverse, well-characterised samples has led to an increased emphasis on collaborative research, often on an international scale. Consequently, it is very common for the sharing of samples such as blood and plasma, as well as data, to take place amongst large and often international groups, and samples are routinely split and shared across national borders.

In this sense, the mechanism and aims of genomic research and its applications in medicine could be described as being subject to globalisation. Regulation at global and international levels is, unsurprisingly, not a straightforward matter. With these global factors in mind, it is worthwhile considering the regulation of the research conducted by international consortia of scientists. Indeed, genomic research highlights some of the perennial problems with the current research governance system in the UK. This system relies mainly on the expertise of research ethics committees, however the extent to which these committees' procedures are appropriate for the pivotal position that they have as 'gatekeepers' in the research process is not clear. Furthermore, the fact that existing governance structures and legal frameworks are *nationally*

[4] Kaye, J., P. Boddington, J. de Vries, H. Gowans, N. Hawkins, C. Heeney, K. Melham, "Ethical, Legal and Social Issues Arising from the Use of GWAS in Medical Research", Report for theWellcome Trust, March 2009 http://www.publichealth.ox.ac.uk/helex/images-and-documents/WTConsultancy_for_website_publication_20091022-1.pdf

based, when research is *global*, is also a concern. As alluded to above, the legal framework for research is by no means simple, based, as it is, on a patchwork of laws. The broader research governance landscape is even more complex, contradictory and confusing, with a number of different bodies with specific requirements and guidelines.

These factors in combination often result in duplicity, as well as uncertainty. Nowhere more so, perhaps, than the somewhat confused status of often cited international instruments – which have clear 'ethical roots' – when compared with hard, binding legal documents. For example, the Council of Europe's Convention on Human Rights and Biomedicine[5] (together with its Additional Protocols on biomedical research[6] and genetic testing for health purposes[7]) is neither signed nor ratified by the UK. Many other European nations have not yet signed or ratified the Convention, a fact which has not been missed by courts in the UK[8] or the EC[9], who can only consider such instruments as being indicative of ethical concerns, and merely persuasive. In a similar vein, the European Court of Human Rights has recently upheld a Swedish court's ruling that national laws governing biomedical research have supremacy over the Declaration of Helsinki [10] where it has not been enshrined into law (as is the case in the UK, outside the area of clinical trials regulation).[11] Interestingly, two of the judges in Strasbourg handed down a dissenting opinion, suggesting that the Declaration of Helsinki was too readily dismissed by the courts.

This all adds to what can already be a frustrating situation for those who are keen to conduct ethically and legally 'compliant' research, and so too those who wish to promote the application of resulting technologies. If left unchecked, the existing governance systems run the risk of impeding emerging biotechnologies.

Related to such matters, HeLEX has been instrumental in the creation of a recent document proposing the development of a global ethical, legal and social implications (ELSI) strategy for genomic medical research. This 'Global ELSI' strategy was written in response to a paper published by the US National

[5] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997) available at http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

[6] Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Strasbourg, 25.I.2005) available at http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm

[7] Council of Europe, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes (Strasbourg, 27.XI.2008) available at http://conventions.coe.int/Treaty/en/Treaties/Html/203.htm

[8] *White v Taylor* [2004] EWCA Civ 1511 at [41]

[9] *De Fruytier (Taxation)* [2010] EUECJ C-237/09 at [27]
[10] Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18thWMA General Assembly, Helsinki, Finland, June 1964 (*as amended*)
[11] *Gillberg v Sweden* 41723/06 [2010] ECHR 1676

Human Genome Research Institute (NHGRI) in Nature earlier in 2011.[12] That paper articulated a vision for how genomics research needs to progress if it is to realise the promise of a "genomic medicine" that grounds clinical care in genomic information. The NHGRI plan emphasised that global action and coordination by the scientific community is required to achieve this vision. It also sketches some of the key ELSI concerns that need to be addressed – from narrow research design issues to broader societal concerns. The view of HeLEX, and the Global ELSI co-authors, is one of concern that, unless this ELSI research is also done in a global, systemic and co-ordinated manner, we will not have the appropriate tools, protocols, infrastructure and policies in place to enable this scientific vision be realised. The Global ELSI document is freely available on the HeLEX website.[13]

8 Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

14 To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

Regulation will, in practice, depend upon a complex mix of factors including the legal, political and social
environment in which they are embedded. New technologies may be developed, applied and adopted in different 'regulatory environments' simultaneously, or at various stages of their development and innovation. Regulatory environments are a complex mix of regulatory institutions and actors, policies, instruments, principles, procedures, practices and norms that have 'a certain coding for action, a coding that signals whether various acts will be viewed positively, negatively or neutrally, whether they are incentivised or disincentivised.'[14] In the regulatory environment of health, a fundamental principle is respect for autonomy and a regulatory framework has been built around informed consent. It is required by research ethics committees and is enshrined in legislation and codes of practice and has become a feature of the regulatory design. That said, debates about the appropriateness of consent – in all of its variations – have been rife for many years, and show no signs of diminishing.

[12] Green, E, Guyer MS and the National Genome Research Institute, Charting a course for genomic medicine from base pairs to
bedside Nature Volume: 470, 204–213 (10 February 2011) doi:10.1038/nature09764
[13] Kaye J, Meslin E, Knoppers BM, Juengst E, Global ELSI– A Research Strategy for Genomics (21 April 2011)
http://www.publichealth.ox.ac.uk/helex/news/news/developing-a-global-vision-for-the-future-of-elsi-research
[14] Brownsword R & Somsen H 'Law, Innovation and Technology: BeforeWe Fast Forward- A Forum for Debate' (2009) 1 Law,
Innovation and Technology 1

The future affordability and effectiveness of health policies depends to a considerable extent on the success of developing certain emerging biotechnologies, and their speedy subsequent translation into successful clinical outcomes. In terms of the regulation of emerging biotechnologies related to health, in our opinion there is not yet clear evidence as to whether there are common legal issues that should be considered. Similarly, we would consider it too difficult to say if such biotechnologies would benefit from a health-specific regulatory framework, or a broader one. That said, our comments above as to the frustration created by the complicated patchwork of laws and ethical guidelines would suggest that a streamlined approach would be beneficial.