

Global ELSI– A Research Strategy for Genomics

On the 10th of February 2011 the U.S. National Human Genome Research Institute (NHGRI) published a paper in *Nature*¹ that articulates its vision for how genomics research needs to progress if it is to realize the promise of a “genomic medicine” that grounds clinical care in genomic information. That plan emphasizes that global action and co-ordination by the scientific community is required to achieve this vision. It also sketches some of the key ethical, legal and social implications (ELSI) that need to be addressed – from narrow research design issues to broader societal concerns. Our concern is 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.

Currently, ELSI research in genomics is carried out across the world in a siloed, parochial, and uncoordinated way – carried out by individuals or small research teams focusing on context-specific concerns that may vary widely between nations and regions. There is often duplication of effort, a failure to learn from others. As the research design challenges facing human genomics investigators have become more pressing, ELSI research has become largely reactive rather than anticipating future developments in science. While not all of the ELSI research must be aimed at delivering practical solutions for the implementation of scientific agendas, it is reasonable to expect that more of the ELSI research agenda should be focused on **anticipating** the future challenges that are raised by genomic science and medicine.

To borrow an analogy from the genome project itself, while the ELSI agenda has been “mapped” to a certain extent (issues have been well identified and described) many of the issues have yet to be deeply “sequenced” – that is, described in granular detail to show the key factors, considerations, and impediments to implementing the hoped-for genomic future. Indeed, there is sufficient scepticism about the promises of genomic medicine that unless these issues are understood in detail, it may soon be impossible to take advantage of the science. In other words, we need to start thinking about the ELSI equivalent of “functional” genomics – of figuring out how the ELSI issues will influence the **implementation** of genomic medicine into society. Just as in genomic research, this requires attending to variation as well, and conducting the kinds of comparative ELSI research that can illuminate key common issues and uncover potential policy solutions.

It is now the time to **build** an ELSI research infrastructure that has the breath of vision and is on an international scale comparable with the Human Genome Project. Otherwise we run the risk that there will not be the infrastructure in place to support future genomic science and medicine, and that our separate efforts will continue to lack the robustness that a comparative, coordinated approach could provide.

To maintain credibility and the integrity of this initiative, it must not be seen to be partisan or exclusive but should be focussed on the common endeavour. The secretariat will be based in P³G – an international organization (<http://www.p3g.org/>) for the harmonization of population studies and ELSI issues that has the expertise to co-ordinate international activity of this kind. It will seek funding from a variety of public, private and philanthropic bodies to reflect the diversity of interests involved and to ensure that this independence is maintained.

¹ Green, E., Guyer M.S. and the National Genome Research Institute 2011 Charting a course for genomic medicine from base pairs to bedside *Nature* Volume: 470, 204–213 (10 February 2011) doi:10.1038/nature09764

The aim of this endeavour is to develop a global ELSI research strategy for genomic science and medicine that would:

1. Map in detail the research that has already been done in the ELSI field in order to identify the areas that need further enquiry to enable and facilitate genomic science and medicine.
2. Identify the additional mechanisms needed to co-ordinate global ELSI research in genomics based on current expertise and knowledge that takes advantage of the many programs, centres, institutions, departments, and organizations committed to funding, conducting, and evaluating ELSI research.
3. Develop a co-ordinated strategy and timetable, using the Human Genome Project as a model, to approach funders to join a coordinated funding programme to finance this global strategy.

The outcome will be a roadmap for ELSI research that can be used for directing and informing the commissioning and funding of ELSI research. On the basis of this roadmap, ELSI research can start to be planned in a systematic, co-ordinated way at a global level. This will enable a clearer vision for the future and will enable researchers to indicate how their research proposal fits into this global strategic vision.

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Dr. Jane Kaye
Director, Centre for Health, Law and Emerging Technologies (HeLEX)
University of Oxford
Oxford OX3 7LF
United Kingdom
jane.kaye@law.ox.ac.uk

Dr. Eric M. Meslin
Director, Indiana University Center for Bioethics
Indianapolis, Indiana
USA 46202
emeslin@iupui.edu

Prof. Bartha Knoppers
Canada Research Chair in Law and Medicine
Director, Centre of Genomics and Policy
Chair of P³G
Faculty of Medicine, Dept. of Human Genetics McGill University
740 Dr. Penfield Avenue, Montreal, QC, Canada H3A 1A4
bartha.knoppers@mcgill.ca

Prof. Eric T. Juengst
Director, UNC Center for Bioethics
Professor, Department of Social Medicine
Professor, Department of Genetics
333 MacNider Hall, Campus Box 7240
University of North Carolina, Chapel Hill
333 S. Columbia Road, Chapel Hill, NC 27599-7240
ejuengst@med.unc.edu