

RESEARCH PRIORITIES

ELSI 2.0 for Genomics and Society

Jane Kaye,^{1*} Eric M. Meslin,² Bartha M. Knoppers,³ Eric T. Juengst,⁴ Mylène Deschênes,⁵ Anne Cambon-Thomsen,⁶ Donald Chalmers,⁷ Jantina De Vries,⁸ Kelly Edwards,⁹ Nils Hoppe,¹⁰ Alastair Kent,¹¹ Clement Adebamowo,¹² Patricia Marshall,¹³ Kazuto Kato¹⁴

Anticipating and addressing the ethical, legal, and social implications (ELSI) of scientific developments has been a key feature of the genomic research agenda (1–4). Research in genomics is advancing by developing common infrastructures and research platforms, open access and sharing policies, and new forms of international collaborations (5–12). In this paper we outline a proposal to establish a “collaboratory” (13) for ELSI research to enable it to become more coordinated, responsive to societal needs, and better able to apply the research knowledge it generates at the global level. Current ELSI research is generally nationally focused, with investigator-initiated approaches that are not always aligned with the developments in international genomics research. This makes it difficult to efficiently leverage findings that impact global practice and policy. Moreover, as translational genomic research design challenges become more pressing (14), ELSI research will need to develop greater capacity to respond rapidly to new developments. The ELSI 2.0 Initiative is designed to catalyze international collaboration in ELSI genomics and to enable those in the field to better assess the impact and dynamics of global genome research.

Vision

The aim of ELSI 2.0 is to accelerate the translation of ELSI research findings into practice and policy. To do this, we will build on successful examples of international ELSI research. To succeed, ELSI 2.0 must be grounded in a commitment to the shared values of mutual respect, trust, and active collaboration. It will require the development of new methods and frameworks for the strategic targeting of research to overcome

current barriers to international, interdisciplinary research. Through ELSI 2.0, ELSI researchers can be globally connected while still carrying out locally sensitive research. By enabling large-scale global collaborations among a range of stakeholders, ELSI research will become more effective, efficient and economical, leading to development of better local, regional, and international practice and policy.

Design and Methods: The Collaboratory

The collaborative Web-based infrastructure (see the figure) will be open to all ELSI researchers, national and international agencies, and other research “consumers,” including the general public and advocacy groups. It will provide ways for ELSI research to make an impact on policy and practice. It will be an active, generative space, distinct from discussion boards or networks. The Collaboratory will provide information on research resources, prospective projects, and workspaces for online collaboration, as well as educational webinars and workshops. ELSI 2.0 will facilitate a variety of activities including networking, rapid response, “crowd-sourcing,” modeling, forecasting, and the development of proactive strategies to coordinate and enable international ELSI research.

It will give a sense of the terrain of the international ELSI landscape, which will be used to identify overlaps and similarities that exist in different localities despite there being different national cultures, legal systems, and policy regimes in play. Identifying and appreciating regional differences can strengthen our understanding of the complexity of bioethics issues and provides a basis for shared learning. For example, the works of Phelan *et al.* (15) and Sankar *et al.*

We need an international infrastructure for the ethical, legal and social implications of genomic research.

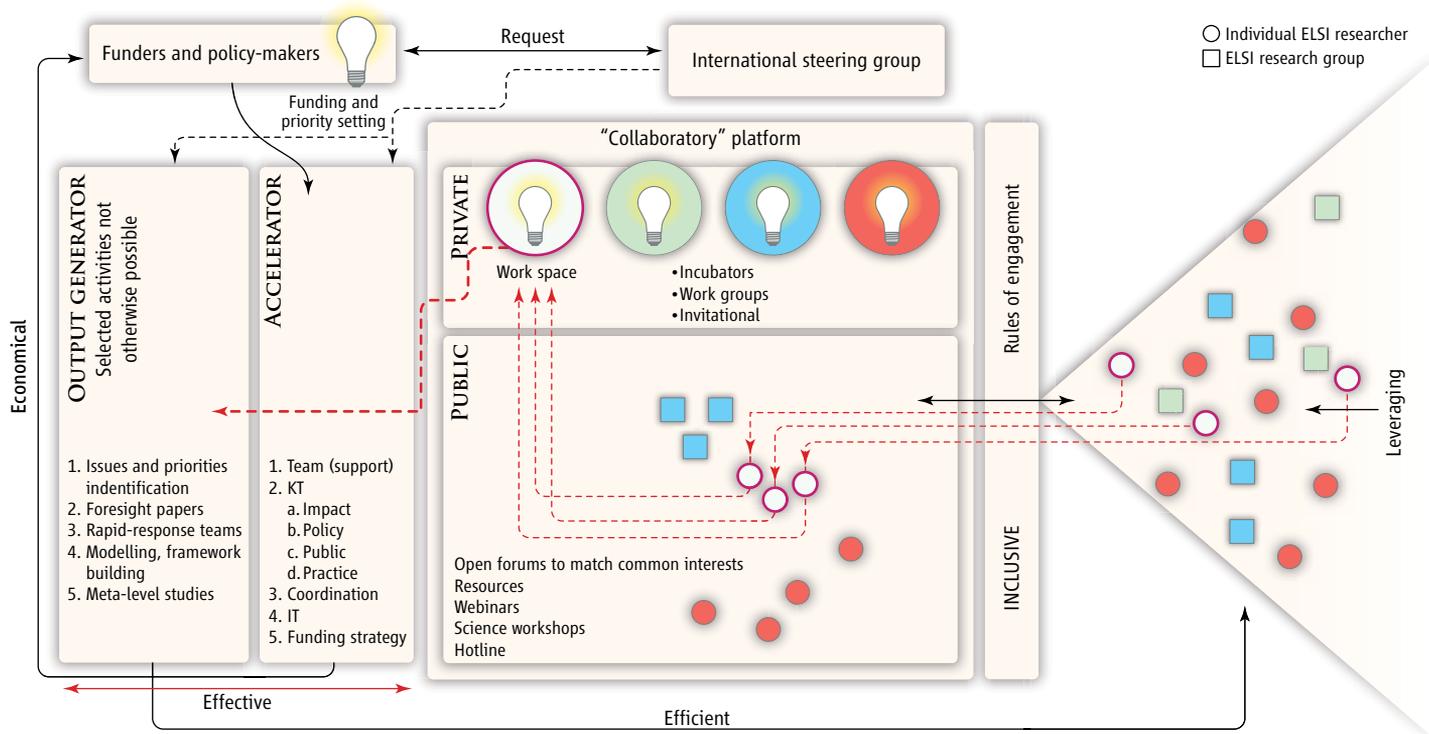
(16) on genetic discrimination are proving to be extremely informative in designing a project on stigma in genomics in Africa. By using ELSI 2.0, tracking and coordinating ELSI research will also be possible at a global level and will accelerate the impact of research on policy.

For an ELSI scholar in Africa, ELSI 2.0 could be a place to connect with other scholars or to tap into resources not otherwise readily available. For a U.S.-based advocacy organization, the Collaboratory will provide essential services to extend the reach of work otherwise locked up in the academic literature. A funder in the European Union could request a rapid response team to respond to ad hoc, short-notice requests related to emerging issues or to forecast important policy directions. A patient could become an active participant in ELSI research or find literature and experts on subjects such as direct-to-consumer testing. For a scholar in Asia looking to fund a multicountry effort, the Collaboratory could help identify funding sources, collaborators, and workshops for the idea. Scholars could choose to be observers or builders and creators (posing projects for a workspace or a crowd-sourced effort) or to motivate collaborators who would not otherwise be accessible (clinicians, patients, policy-makers). In this way, ELSI 2.0 will continually build and support global ELSI research and policy-making capacity.

The Collaboratory will stimulate creativity and communication between researchers, diverse publics, funders, and policy-makers in a variety of ways. It will provide a Web-based infrastructure with the same capabilities as the collective platforms used in large-scale, international genomics science and elsewhere and will draw on a variety of approaches to maximize interactions, including networking, rapid response, crowd-sourcing, modeling, forecasting, and the development of proactive strategies and comparative methodologies to enable international ELSI research in genomics. This will include modeling exercises for the construction of international frameworks and approaches to issues. This effort will promote efficient use of research efforts and resources, avoiding redundancy and duplication of effort. A

¹HelEX, Department of Public Health, University of Oxford OX3 7LF, Oxford UK. ²IU Center for Bioethics, Indiana University, Bloomington, IN 46202, USA. ³Centre for Genomics and Policy, McGill University, Montreal H3A 1A4, Canada. ⁴UNC Center for Bioethics, University of North Carolina, Chapel Hill, NC 27599, USA. ⁵P3G, Montreal H3V 1A2, Canada. ⁶UMR 1027, Inserm, Epidemiology and analyses in public health, 31000 Toulouse, France; UMR 1027, Faculté de médecine Purpan, Université Paul Sabatier Toulouse, 31000 Toulouse, France. ⁷Faculty of Law, University of Tasmania, Hobart, Tasmania 7000, Australia. ⁸Faculty of Health Sciences, University of Cape Town, South Africa. ⁹Department of Bioethics and Humanities, University of Washington, Seattle, WA 98195, USA. ¹⁰CELLS, Leibniz Universität, 30167 Hannover, Germany. ¹¹Genetic Alliance UK, London N1 3QP, UK. ¹²Institute of Human Virology, Garki, Abuja, Nigeria; University of Maryland School of Medicine, Baltimore, MD 21201, USA. ¹³Department of Bioethics, Case Western Reserve University, Cleveland, OH 44106, USA. ¹⁴Osaka University, Suita 565-0871, Japan.

*Author for correspondence. E-mail: jane.kaye@law.ox.ac.uk



Collaboratory scheme. Relations among the parts of the proposed Collaboratory are shown. KT, knowledge transfer; IT, information technology.

clearer understanding of the international ELSI landscape will be invaluable in informing and coordinating future research, tracking the impact of research on policy, and continually building ELSI research and policy-making capacity.

To be fully responsive to emerging issues, the Collaboratory will establish an “Accelerator Team” with experience and skills in the translation and delivery of ELSI research to different publics, patient groups, the media, and policy-makers. It is envisaged that ELSI 2.0 could provide funding organizations with access to reliable assessments of research priorities to assist with the planning of research agendas and strategy.

Together, the users of the Collaboratory infrastructure will develop a governance approach consistent with the vision and values of ELSI 2.0. An international steering group will guide and support the operation and development of the overall initiative. A regular evaluation process with measurable goals and targets will be used to ensure the effectiveness and efficiency of the initiative. ELSI 2.0 will be hosted through the P³G Consortium, which has parallel aims and established policies (17).

Conclusion

The success of ELSI 2.0 will be realized by the energy, enthusiasm, and diversity of those who join and participate. We invite all those interested in ethical, legal, and social issues

in genomics to become involved as active contributors. Initial pilot efforts using current open-source tools will test proof of concept to gauge further support and participation. Our next step will be to have a series of meetings to publicize and gather support for the initiative and details of these meetings, which can be found on the P³G Web site. The first meeting will be held on 26 June 2012 as a satellite workshop of the International Association of Bioethics meeting in Rotterdam (18). We shall pursue an international coordinated funding strategy, as has been achieved for large-scale genome science collaborations like the International Cancer Genome Project (7). Our initial estimates are that establishment costs will be in the region of US\$2 million per year for 2 to 3 years. We believe that ELSI 2.0 has the potential to radically transform and enhance the international genomics and society research agenda. In doing so, it will be possible to better anticipate and address the challenges raised by the globalization of genomic research.

References and Notes

1. F. S. Collins, *N. Engl. J. Med.* **341**, 28 (1999).
2. E. M. Meslin, E. J. Thomson, J. T. Boyer, *Kennedy Inst. Ethics J.* **7**, 291 (1997).
3. E. T. Juengst, *Soc. Philos. Policy* **13**, 63 (1996).
4. A. Wolfe, in *Encyclopedia of Ethical, Legal and Policy Issues in Biotechnology* (Wiley, New York, 2003); 10.1002/0471250597.mur045.10.1002/0471250597.mur045
5. E. Birney *et al.*, *Nature* **461**, 168 (2009).
6. See also ICGC as a model for international collaboration.
7. T. J. Hudson *et al.*, *Nature* **464**, 993 (2010).

8. W. Burke, M. J. Khoury, A. Stewart, R. L. Zimmern, *Genet. Med.* **8**, 451 (2006).
9. E. A. Achidi *et al.*, *Nature* **456**, 732 (2008).
10. P. A. Singer, A. S. Daar, *Science* **294**, 87 (2001).
11. E. Calva, M. J. Cardoso, J. V. Gavilondo, *Trends Biotechnol.* **20**, 368 (2002).
12. T. O. OgunDIRAN, *Soc. Policy* **1**, 66 (2005).
13. W. A. Wulf, *Science* **261**, 854 (1993).
14. E. D. Green *et al.*, *Nature* **470**, 204 (2011).
15. J. C. Phelan, R. Cruz-Rojas, M. Reiff, *Am. J. Psychiatr. Rehabil.* **6**, 159 (2002).
16. P. Sankar, M. K. Cho, P. R. Wolpe, C. Schairer, *Genet. Med.* **8**, 33 (2006).
17. The P³G Consortium is located at McGill University, Montreal, Canada; www.p3g.org/.
18. Online registration is now open at <http://elsirotterdam.eventbrite.com/>.

Acknowledgments: We thank the Brocher Foundation and the Wellcome Trust (097671/Z/11/Z) for their generous support for a meeting held at the Brocher Foundation 16 to 19 November 2011. In addition, the authors are supported under the following grants: J.K., Wellcome Trust (096599/Z/11/Z) and BioSHaRE-EU (261433); E.M.M., Richard M. Fairbanks Foundation and National Center for Research Resources, NIH (UL1RR025761-01); B.M.K., Canada Research Chair in Law and Medicine; Genome Canada/Quebec and BioSHaRE-EU (261433); A.C.-T., CAGEKID (a collaboration on kidney cancer genomics) (241669), BioSHaRE-EU (261433), Genetic European Variation in Disease (GEUVADIS) (261123) and Genotype to Phenotype Databases: A Holistic Approach (GEN2PHEN) (200754); D.C., National Health and Medical Research Council, Australia (490037); J.d.V., Postdoctoral Fellowship from the University of Cape Town; K.E., Center for Genomics and Healthcare Equality, National Human Genome Research Institute (NHGRI), NIH (P50 HG3374); C.A., West African Bioethics Training Program Fogarty International Center (FIC), NIH (R25TW007091); P.M., The Center for Genetic Research Ethics and Law (CGREAL), a Center for Excellence in ELSI Research, NHGRI, NIH (P50-HG-03390-07); K.K., Ministry of Education, Culture, Sports, Science and Technology (MEXT) (22150002), Japan.