Best Practices in Personalized Medicine
Vancouver, BC
March 8-9, 2011

"Workable" Ethics for Translational Research?

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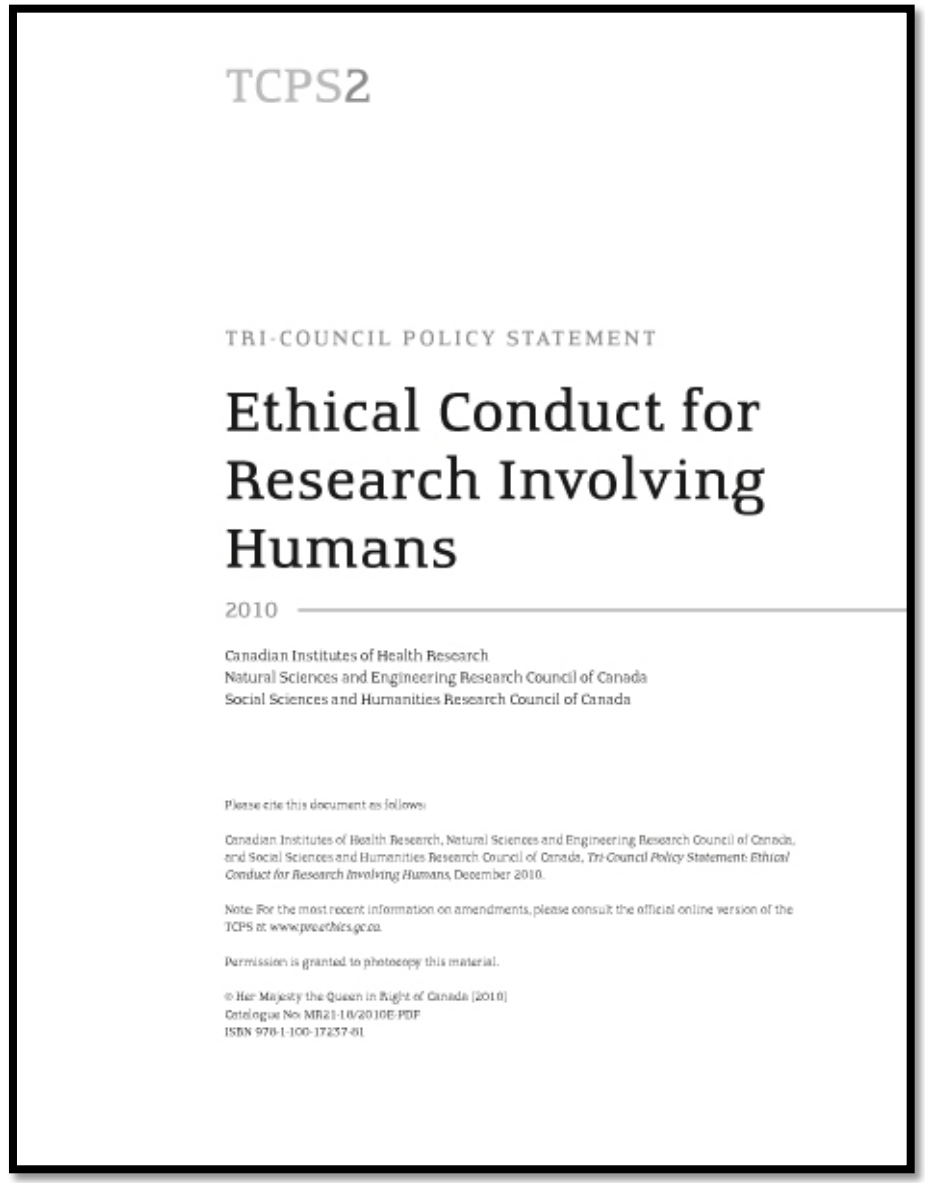
Research Ethics



TCPS2

TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2010

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Please cite this document as follows:

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Note: For the most recent information on amendments, please consult the official online version of the TCPS at *www.pre.ethics.gc.ca*.

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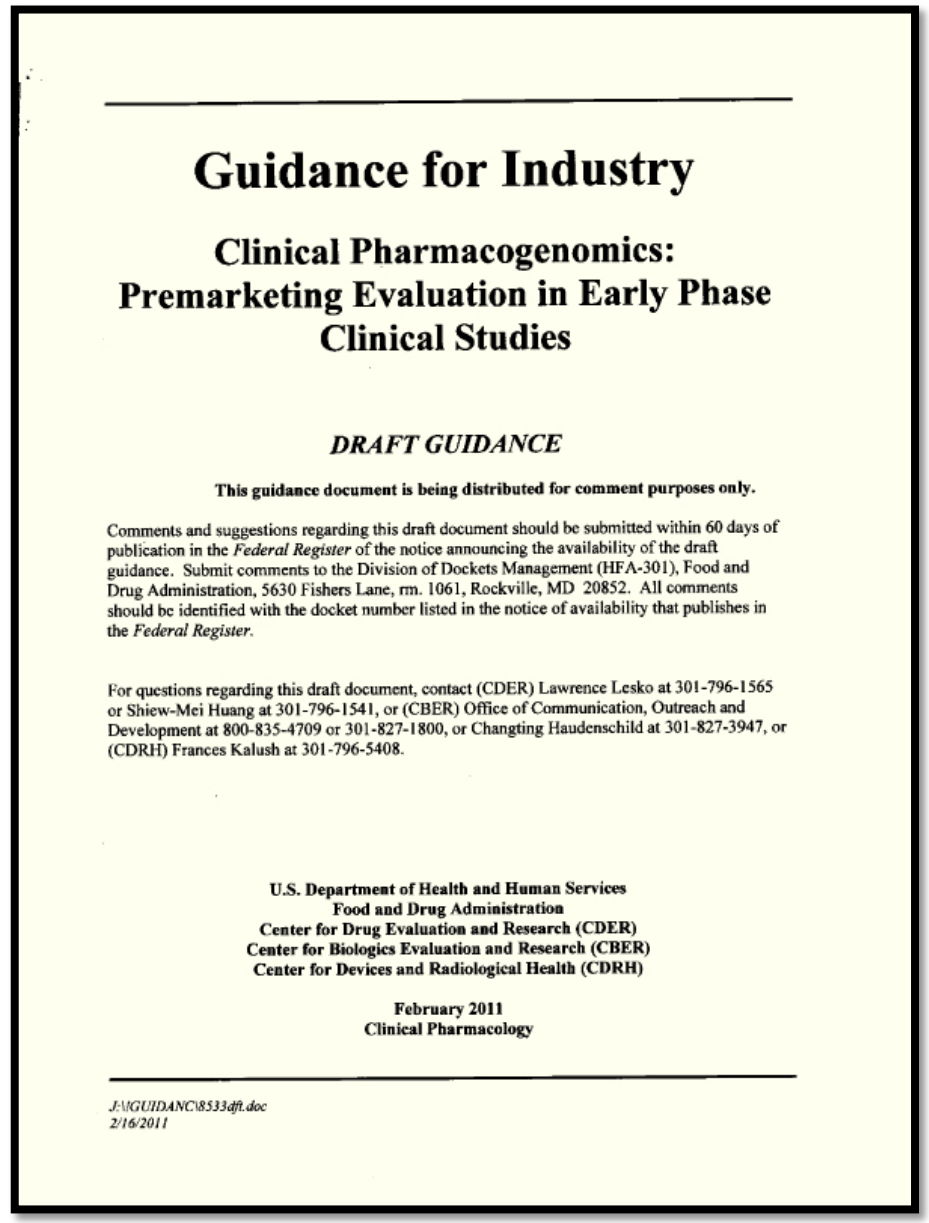
Clinical Trials



Guidance for Industry

Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-301), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Lawrence Lesko at 301-796-1565 or Shiew-Mei Huang at 301-796-1541, or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 301-827-1800, or Changting Haudenschild at 301-827-3947, or (CDRH) Frances Kalush at 301-796-5408.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

February 2011
Clinical Pharmacology

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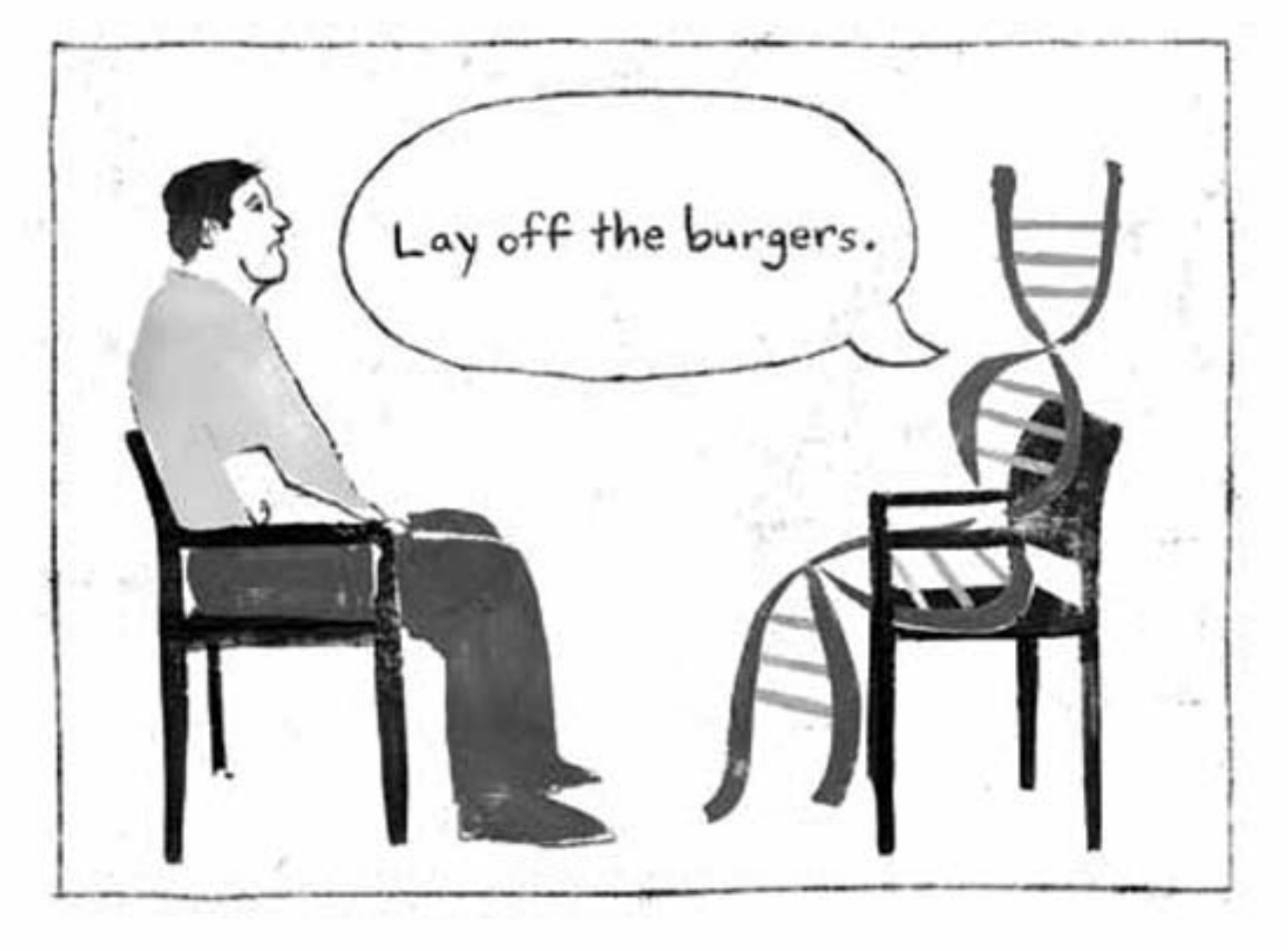
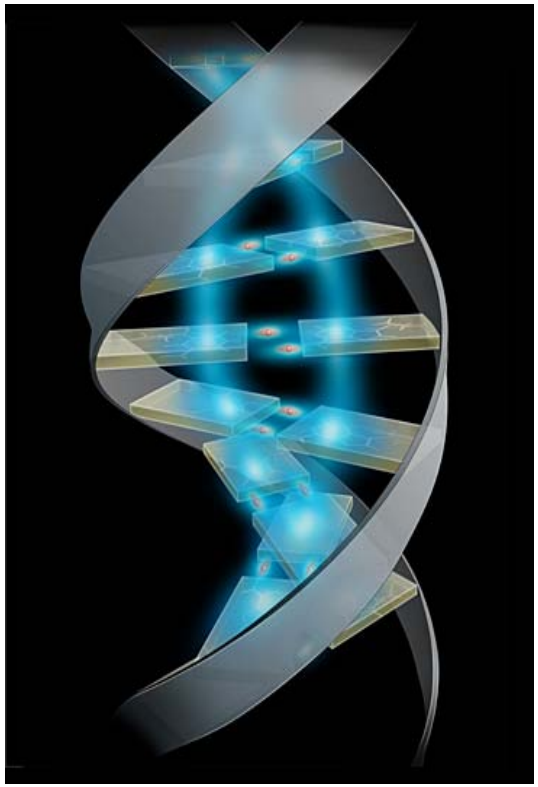
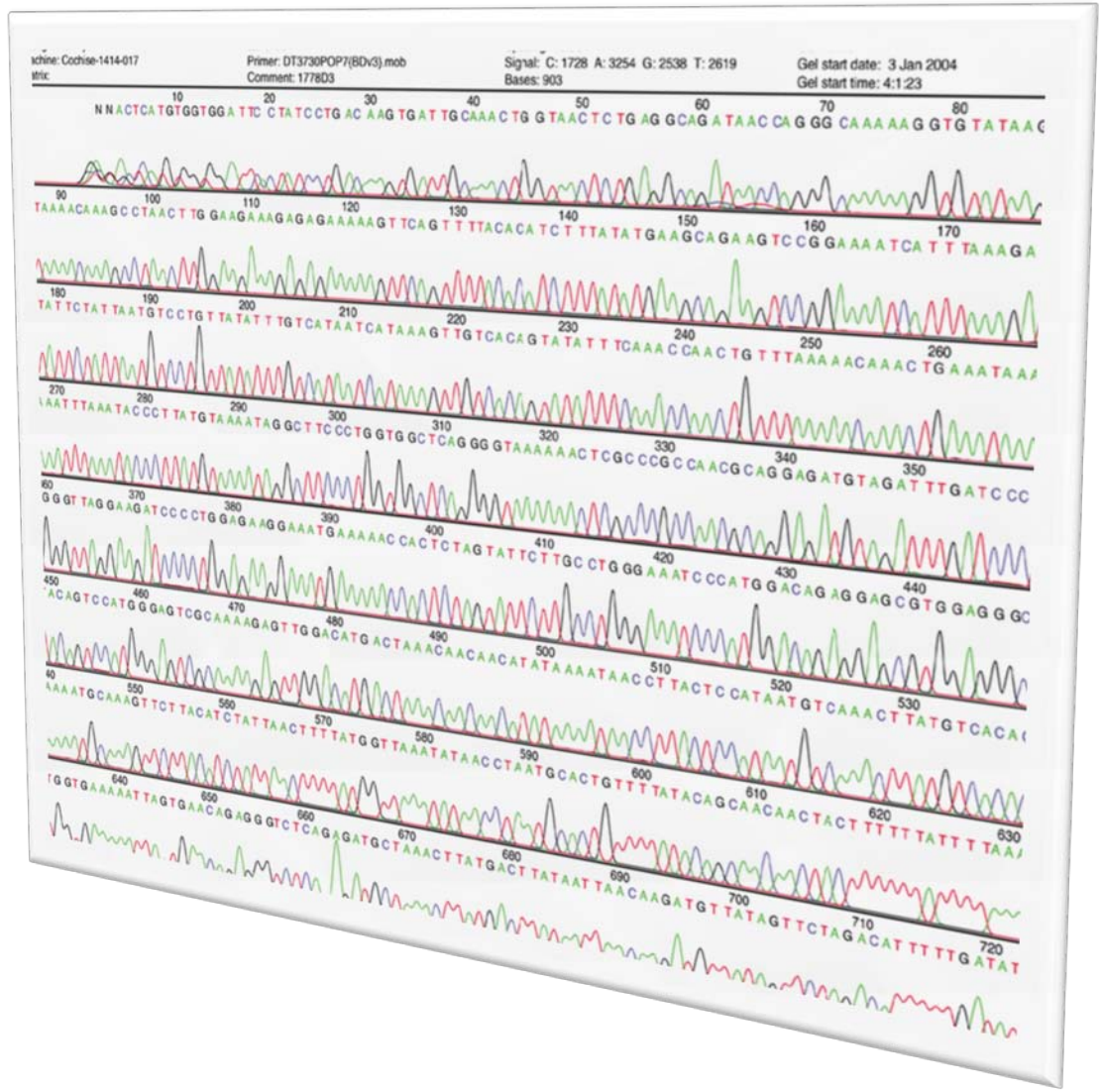
Physician – Patient Relationship



Whole-Genome Sequencing





Population Biobanks

POLICYFORUM

RESEARCH FUNDING

Sustaining the Data and Bioresource Commons

Globalization of biomedical research requires sustained investment for databases and biorepositories.

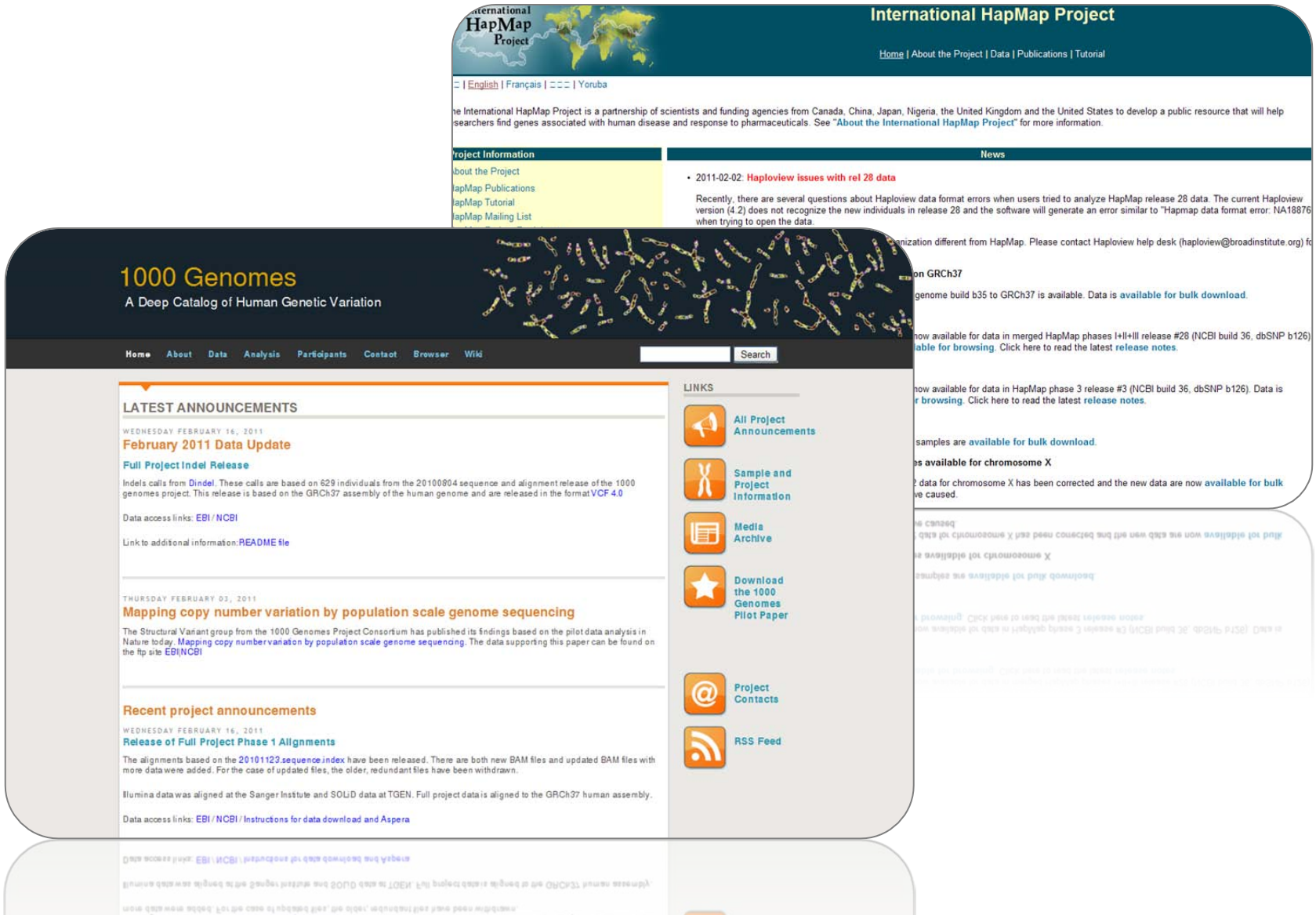
Paul N. Schofield,[1,2*] Janan Eppig,[2] Eva Huala,[3] Martin Hrabe de Angelis,[4] Mark Harvey,[5] Duncan Davidson,[6] Tom Weaver,[7] Steve Brown,[8] Damian Smedley,[9] Nadia Rosenthal,[10] Klaus Schughart,[11] Vassilis Aidinis,[12] Glauco Tocchini-Valentini,[13] John M. Hancock[8]

Development of powerful, high-throughput technologies, together with globalization of scientific research, presents the biomedical research community with unprecedented challenges for the management, archiving, and distribution of data and bioresources (*1*). We need a social contract between funding agencies and the scientific community to accommodate "bottom-up" integration and "top-down" financing of databases and biorepositories on an international scale.

The biological commons is evolving away from a traditional differen-

data models to accommodate new data types. The associated bioontologies and other informatics tools need to continue to be developed, maintained, and applied to data to standardize and maximize access, retrieval, and exploitation for discovery. Repositories also need to innovate and respond to emerging disruptive technologies. Consequently, any distinction between time-delimited research projects and long-term, relatively static infrastructures is being eroded. The traditional distinction between "infrastructure" and "research" is even less appropriate, presenting a challenge to those funders who continue to think in these

HapMap and 1000Genomes



”Citizens” and Population Biobanks

Genotyping and Clinical Trials

Commentary

Ethical challenges in genotype-driven research recruitment

Laura M. Beskow,[1,4] Kristen N. Linney,[2] Rodney A. Radtke,[3] Erin L. Heinzen,[2] and David B. Goldstein[2]

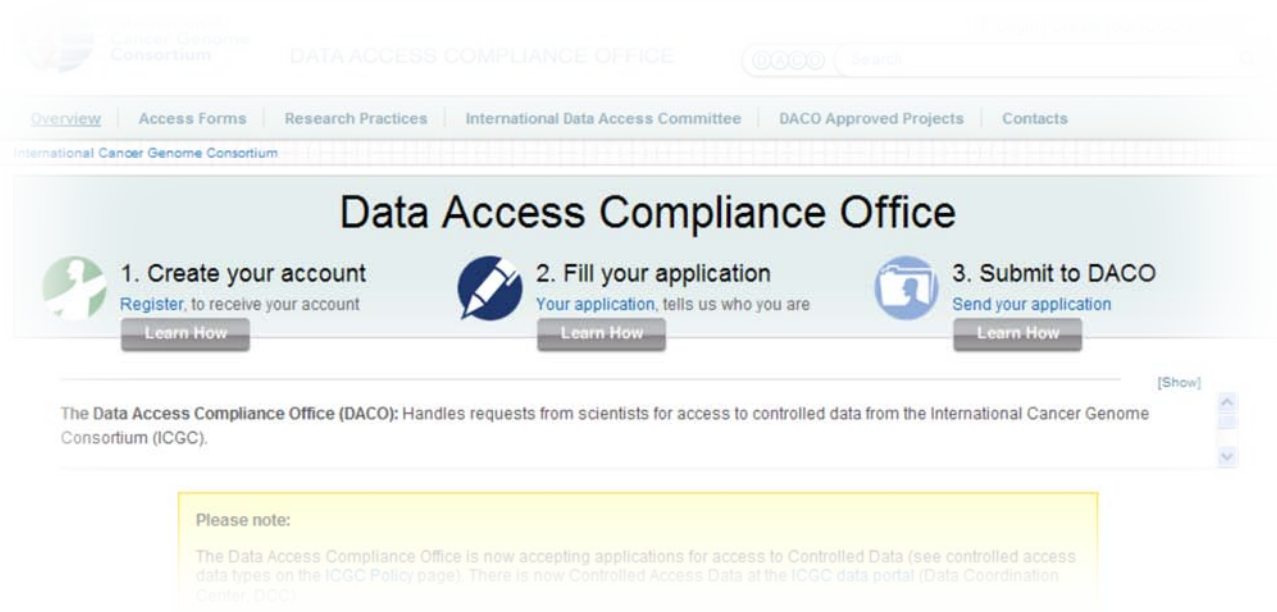
[1]*Center for Genome Ethics, Law and Policy, Duke Institute for Genome Sciences and Policy, Durham, North Carolina 27708, USA*
[2]*Center for Human Genome Variation, Duke Institute for Genome Sciences and Policy, Durham, North Carolina 27708, USA;*
[3]*Department of Medicine, Division of Neurology, Duke University Medical Center, Durham, North Carolina 27710, USA*

Many genetic and genomic studies are conducted using a phenotype-driven approach: Cases and controls are identified based on the presence or absence of a particular condition and analyses are undertaken to identify gene variants associated with that condition. The inverse—a genotype-driven approach—is receiving increasing attention as another powerful research tool. In this

from among patients attending adult and pediatric epilepsy clin
at Duke; subjects in another study on the genetics of mem
served as controls. The consent form for the epilepsy study sta
that participants would not receive individual research results (B
1). Participants were also asked to sign a separate "biobankir
consent form to permit the long-term storage of biological v

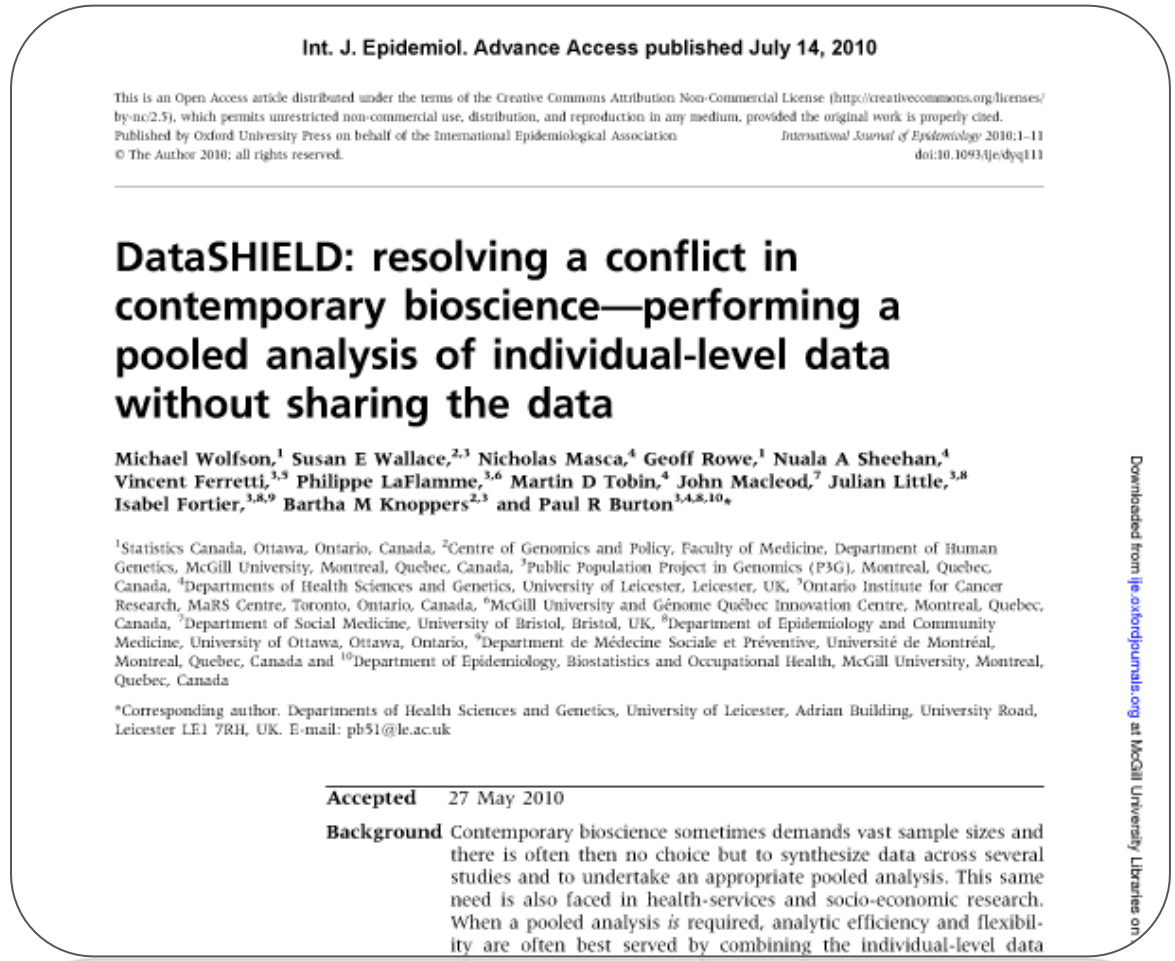
Personal Genome Project

Controlled Access Databases (ICGC)



International Cancer Genome Consortium

DataSHIELD



Int. J. Epidemiol. Advance Access published July 14, 2010

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International Journal of Epidemiology 2010;1–11
doi:10.1093/ije/dyq111

DataSHIELD: resolving a conflict in contemporary bioscience—performing a pooled analysis of individual-level data without sharing the data

Michael Wolfson,[1] Susan E Wallace,[2,3] Nicholas Masca,[4] Geoff Rowe,[1] Nuala A Sheehan,[4] Vincent Ferretti,[3,5] Philippe LaFlamme,[3,6] Martin D Tobin,[4] John Macleod,[7] Julian Little,[3,8] Isabel Fortier,[3,8,9] Bartha M Knoppers[2,3] and Paul R Burton[3,4,8,10]*

[1]Statistics Canada, Ottawa, Ontario, Canada, [2]Centre of Genomics and Policy, Faculty of Medicine, Department of Human Genetics, McGill University, Montreal, Quebec, Canada, [3]Public Population Project in Genomics (P3G), Montreal, Quebec, Canada, [4]Departments of Health Sciences and Genetics, University of Leicester, Leicester, UK, [5]Ontario Institute for Cancer Research, MaRS Centre, Toronto, Ontario, Canada, [6]McGill University and Génome Québec Innovation Centre, Montreal, Quebec, Canada, [7]Department of Social Medicine, University of Bristol, Bristol, UK, [8]Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, Ontario, [9]Department de Médecine Sociale et Préventive, Université de Montréal, Montreal, Quebec, Canada and [10]Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montreal, Quebec, Canada

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Accepted 27 May 2010

Background Contemporary bioscience sometimes demands vast sample sizes and there is often then no choice but to synthesize data across several studies and to undertake an appropriate pooled analysis. This same need is also faced in health-services and socio-economic research. When a pooled analysis *is* required, analytic efficiency and flexibility are often best served by combining the individual-level data

Identification?

OPEN ACCESS Freely available online

PLoS GENETICS

Viewpoints

Public Access to Genome-Wide Data: Five Views on Balancing Research with Privacy and Protection

P³G Consortium*, George Church[1]*, Catherine Heeney[2]*, Naomi Hawkins[2], Jantina de Vries[2], Paula Boddington[2], Jane Kaye[2], Martin Bobrow[3]*, Bruce Weir[4]*

1 Department of Genetics, Harvard Medical School, Cambridge, Massachusetts, United States of America, 2 The Ethox Centre, Department of Public Health and Primary Care, University of Oxford, Oxford, United Kingdom, 3 Department of Medical Genetics, University of Cambridge, Cambridge, United Kingdom, 4 Department of Biostatistics, University of Washington, Seattle, Washington, United States of America

Introduction by Greg Gibson and Elizabeth Fisher

Just over twelve months ago, *PLoS Genetics* published a paper [1] demonstrating that, given genome-wide genotype data from an individual, it is, in principle, possible to ascertain whether that individual is a member of a larger group defined solely by aggregate genotype frequencies, such as a forensic sample or a cohort of participants in a genome-wide association study (GWAS). As a consequence, the National Institutes of Health (NIH) and Wellcome Trust agreed to shut down public access not just to individual genotype data from an individual, it is, in principle, possible to ascertain whether that individual is a member of a larger group defined solely by aggregate genotype frequencies, such as a forensic sample or a cohort of participants in a genome-wide association study (GWAS). As a consequence, the National Institutes of Health (NIH) and Wellcome Trust agreed to shut down public access not just to individual geno-

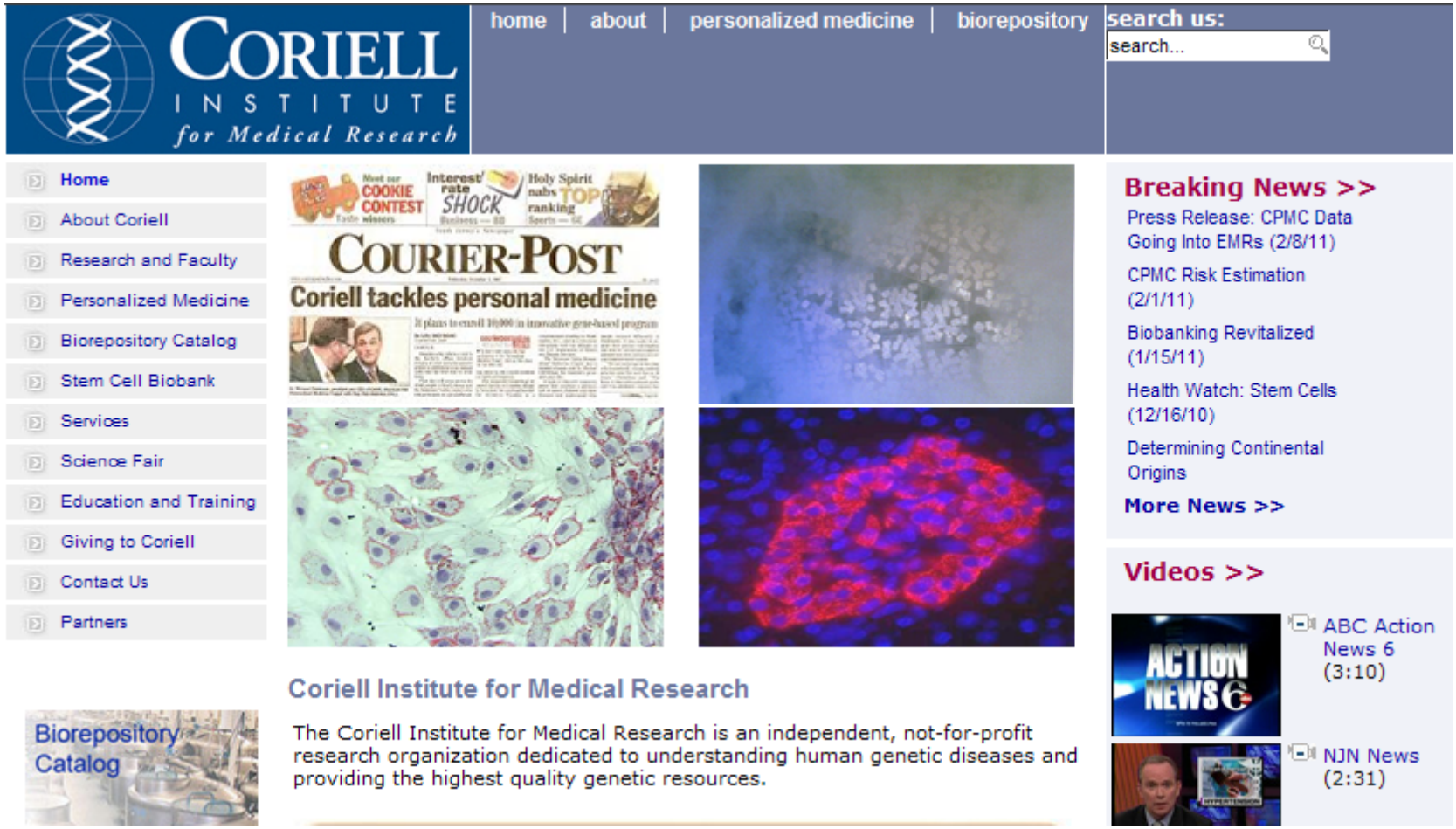
research. George Church posits that actions directed toward restricting data access are likely to exclude researchers who might provide the most novel insights into the data and instead makes the argument that full disclosure and consent to the release of genomic information should be sought from study participants, rather than making difficult-to-guarantee promises of anonymity. Martin Bobrow weighs the risks and benefits and proposes four steps that represent a middle ground: Retain restricted access for now, make malicious de-identification practices illegal, increase public awareness of the issues, and encourage recognition that scientists

DNA mixture including up to 1,000 participants. Although in hindsight it is clear that basic statistical theory would predict this to be the case, the reality is that it had previously gone completely unrecognised.

This situation illustrates the need to raise the level of discussion, thereby avoiding the ad hoc resolution of immediate privacy concerns and anticipating future scientific possibilities with a view to providing prospective guidance.

The implications of the Homer paper were discussed by the international Public Population Project in Genomics (P³G) (http://www.p3g.org). The consensus was

Biobanks Websites



Return of Results?

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THE JOURNAL OF
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A Journal of the American Society of Law, Medicine & Ethics

Lexicon
International Context and General Principles
Biobanks and Populations
Paediatric Research
Intrafamilial Communication
Deceased Individuals
International Consortia

"Incidental" Findings

Data-Sharing

International Code of Conduct for Data Sharing in Genomic Research

Genomic Research: Quo Vadis?

PERSPECTIVE

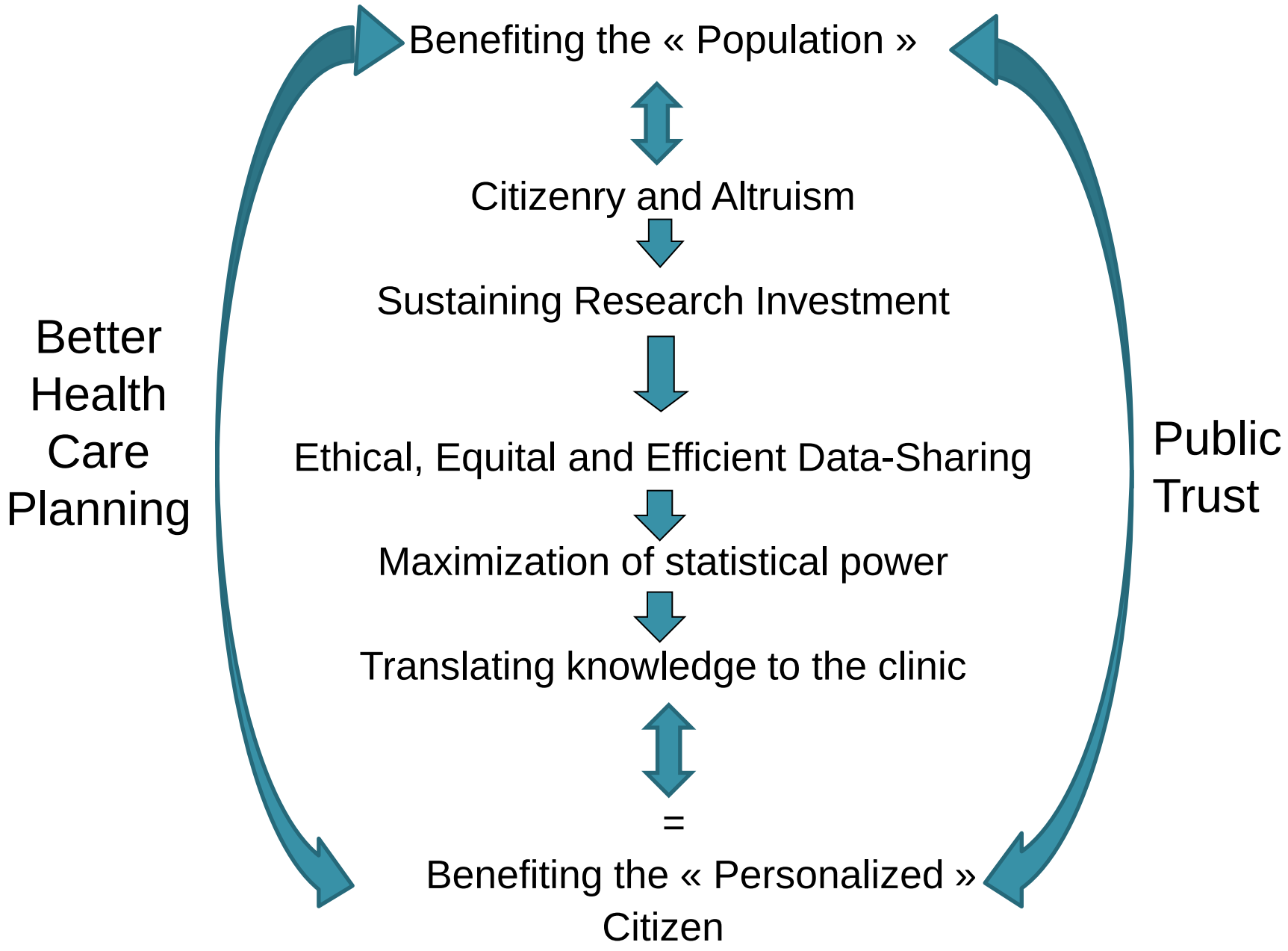
doi:10.1038/nature09764

Charting a course for genomic medicine from base pairs to bedside

Eric D. Green[1], Mark S. Guyer[1] & National Human Genome Research Institute*

There has been much progress in genomics in the ten years since a draft sequence of the human genome was published. Opportunities for understanding health and disease are now unprecedented, as advances in genomics are harnessed to obtain robust foundational knowledge about the structure and function of the human genome and about the genetic contributions to human health and disease. Here we articulate a 2011 vision for the future of genomics research and describe the path towards an era of genomic medicine.

CONCLUSION


Benefiting the « Population »
Citizenry and Altruism
Sustaining Research Investment
Ethical, Equital and Efficient Data-Sharing
Maximization of statistical power
Translating knowledge to the clinic
=
Benefiting the « Personalized » Citizen
Better Health Care Planning
Public Trust