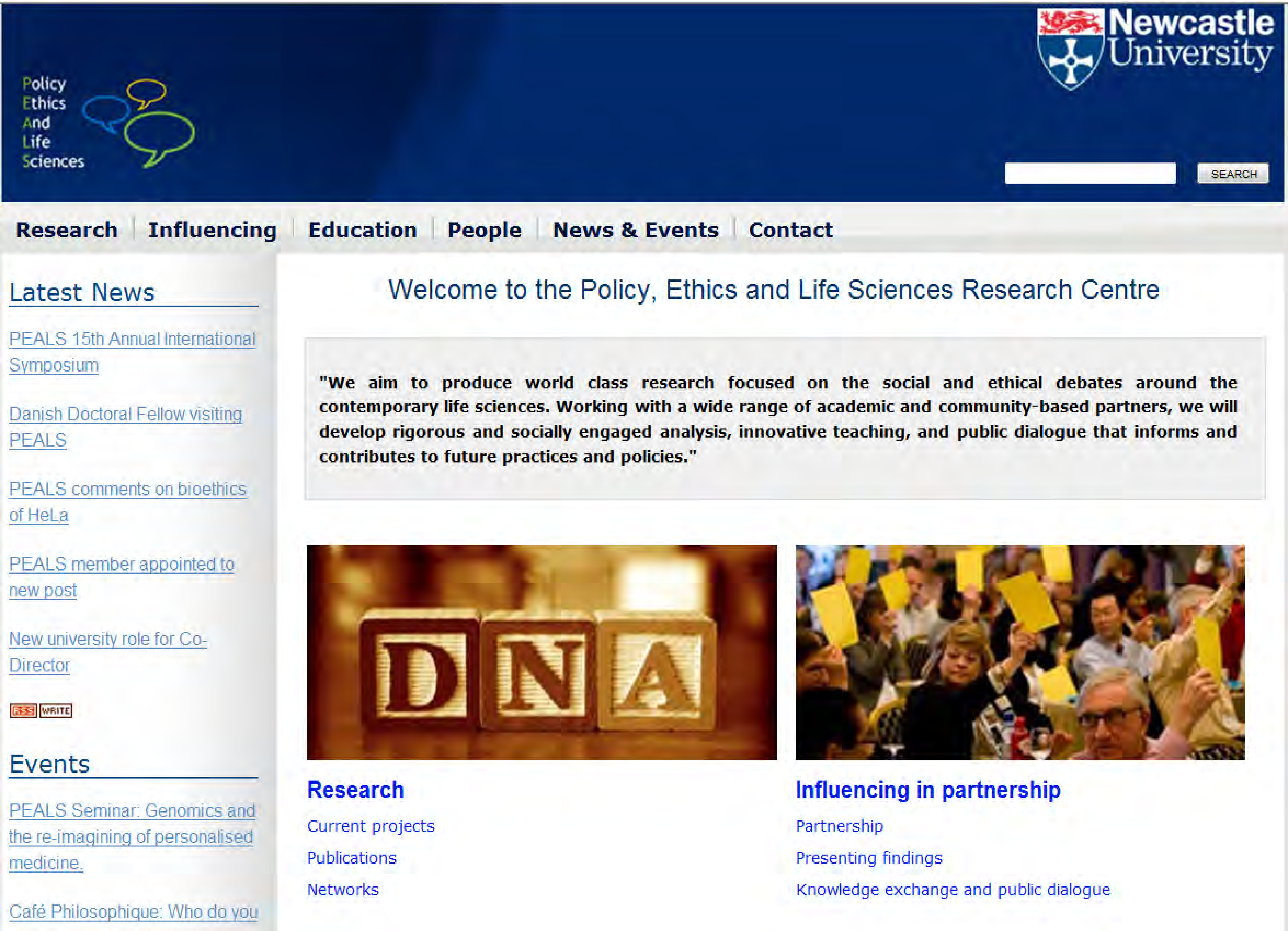
DATA/ SAMPLE SHARING FOR RESEARCH: ETHICAL QUESTIONS

Dr Simon Woods, PEALS (Policy, Ethics & Life Sciences) Research Centre, Newcastle University



Latest News

PEALS 15th Annual International Symposium

Danish Doctoral Fellow visiting PEALS

PEALS comments on bioethics of HeLa

PEALS member appointed to new post

New university role for Co-Director

Events

PEALS Seminar: Genomics and the re-imagining of personalised medicine.

Café Philosophique: Who do you

Welcome to the Policy, Ethics and Life Sciences Research Centre

"We aim to produce world class research focused on the social and ethical debates around the contemporary life sciences. Working with a wide range of academic and community-based partners, we will develop rigorous and socially engaged analysis, innovative teaching, and public dialogue that informs and contributes to future practices and policies."

Research

Current projects

Publications

Networks

Influencing in partnership

Partnership

Presenting findings

Knowledge exchange and public dialogue

Session aims

☐ This session will outline some of the social and ethical debates related to research involving ‘big data’ sharing (Biobanks and Databases) .

☐ Provide an overview of the issues with reference to a series of cases studies

☐ Provide an opportunity to ask questions and reflect upon the key issues

The rare disease agenda

- Importance/necessity of data sharing (hostage to fortune)
- Patient power (self-starting, political activists)
- Necessarily international – global sharing
- Paediatric context (family) – ‘vulnerable’ ‘subjects’
- Leap of faith/‘forced’ to trust or genuine trust?

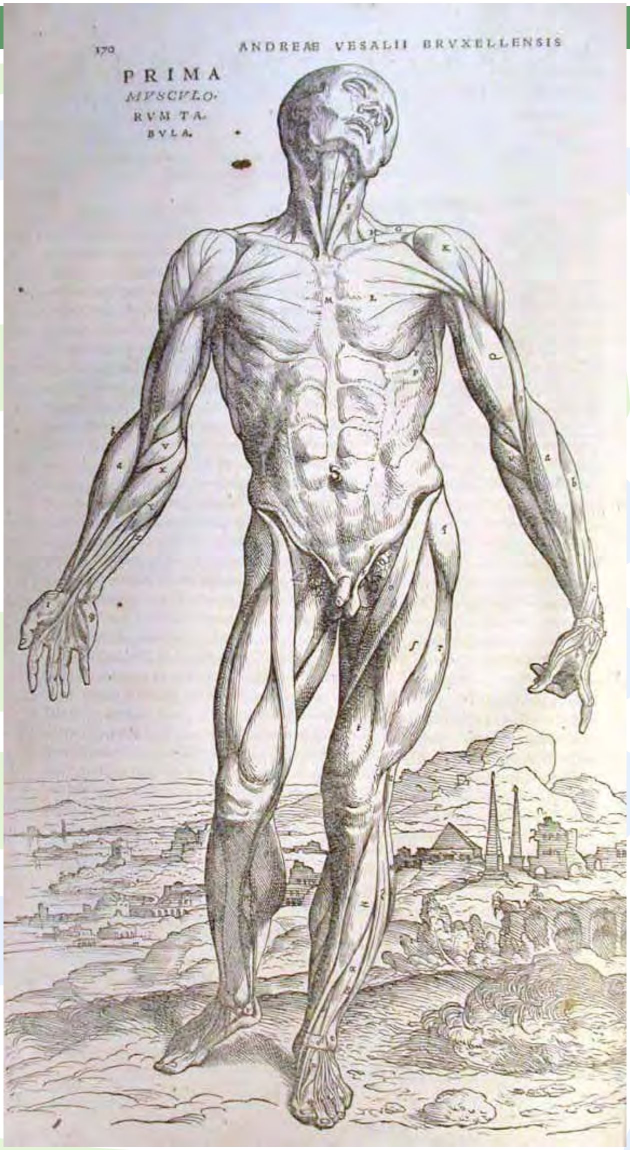
Medicine and the body

The body: as a resource for medicine

- Leonard da Vinci
- Vesalius: 16thC *De humani corporis fabrica*

Sought to describe, understand and explain the body (vivisection/ post-mortem – usual of the 'criminal' body)

http://www.stanford.edu/class/history13/earlysciencelab/body/bodymaincopy.html



Res nullius – no-one's thing

- ☐ Long history of collecting and exploiting the human body for medical purposes
- ☐ 'Body snatching' to sell to anatomists
- ☐ Grave robbers left grave clothes and personal effects since these were property and the body was not. So to avoid charges of theft the bodies were delivered naked to the anatomists.
- ☐ Hunter and the 'Irish Giant'

James Blake Bailey

Henrietta Lacks and the HeLa Cell line

Taken with out consent and distributed world-wide

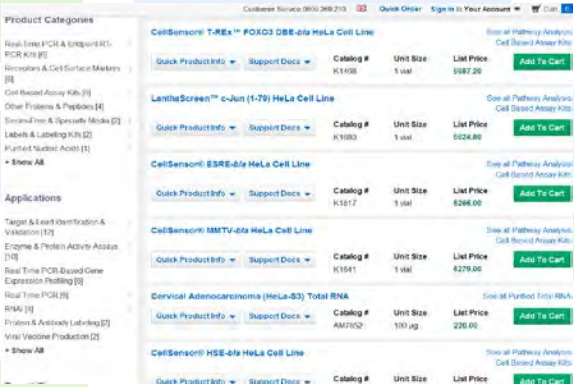
Contributed to development of e.g. Polio vaccine, pioneering cancer research.

Ubiquitous in biomedical laboratories but always know as HeLa (Henrietta was never acknowledged and her family never knew of the use of her tissues)

Eventually when told of these ‘immortal’ cells they thought that

- ☐ Henrietta Lacks died of a very aggressive cervical cancer, a biopsy from her cancer produced a prolific ‘cell line’ – an ‘immortal’ source of replenished cells invaluable for research.

(August 1, 1920 – October 4, 1951)



Product Categories

Applications

CellSensor® T-REx™ FOXO3 DBE-bla HeLa Cell Line

LanthaScreen™ c-Jun (1-79) HeLa Cell Line

CellSensor® ESRE-bla HeLa Cell Line

CellSensor® MMTV-bla HeLa Cell Line

Cervical Adenocarcinoma (HeLa-S3) Total RNA

CellSensor® HSE-bla HeLa Cell Line

Skloot R (2010) The Immortal Life of Henrietta Lacks. Pan Books

Henrietta Lacks and the HeLa Cell line

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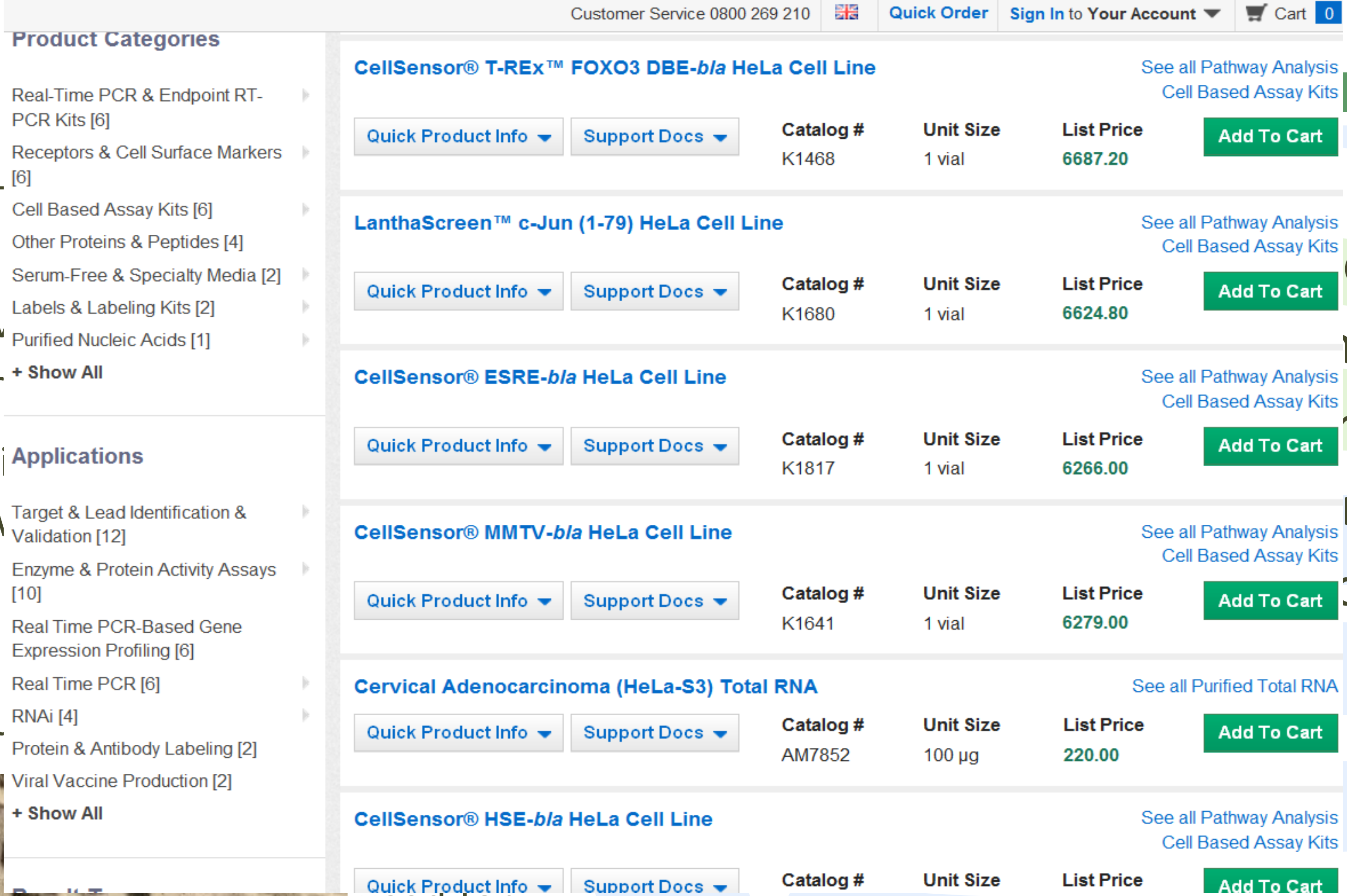


Product Categories

- Real-Time PCR & Endpoint RT-PCR Kits [6]
- Receptors & Cell Surface Markers [6]
- Cell Based Assay Kits [6]
- Other Proteins & Peptides [4]
- Serum-Free & Specialty Media [2]
- Labels & Labeling Kits [2]
- Purified Nucleic Acids [1]
- + Show All

Applications

- Target & Lead Identification & Validation [12]
- Enzyme & Protein Activity Assays [10]
- Real Time PCR-Based Gene Expression Profiling [6]
- Real Time PCR [6]
- RNAi [4]
- Protein & Antibody Labeling [2]
- Viral Vaccine Production [2]
- + Show All

Product	Catalog #	Unit Size	List Price
CellSensor® T-REx™ FOXO3 DBE-*bla* HeLa Cell Line	K1468	1 vial	6687.20
LanthaScreen™ c-Jun (1-79) HeLa Cell Line	K1680	1 vial	6624.80
CellSensor® ESRE-*bla* HeLa Cell Line	K1817	1 vial	6266.00
CellSensor® MMTV-*bla* HeLa Cell Line	K1641	1 vial	6279.00
Cervical Adenocarcinoma (HeLa-S3) Total RNA	AM7852	100 µg	220.00
CellSensor® HSE-*bla* HeLa Cell Line			

Skloot R (2010) The Immortal Life of Henrietta Lacks. Pan Books

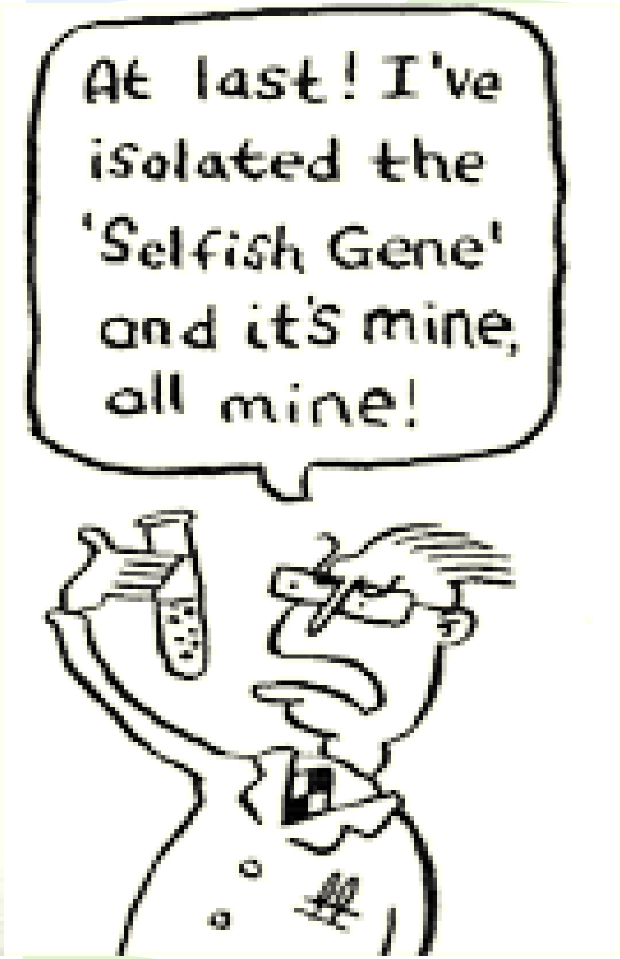
Patenting life

- *Diamond v Chakrabarty 1980*

Title 35 U.S.C. 101 provides for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or composition of matter." Respondent filed a patent application relating to his invention of a human-made, genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria.

- Jasanoff, *S. Designs on Nature: Science and Democracy in Europe and the* US (Princeton: Princeton University Press, 2005)

- www.hgalert.org/



Moore: value in the body

- 1976 John Moore – who had a rare leukaemia (Hairy-Cell Leukaemia) was also discovered to be the source of a highly exploitable/ highly valuable cell line (The ‘Mo’ line)
- In addition to being treated for his condition (which included the removal of his spleen) spleen tissue, blood and other bio samples were obtained over a period of years for the purposes of research.
- Moores’s doctors, Golde and Quan filed for patents on the ‘products’ of these tissues because they were very powerful biological agents. (valued circa $15million)
- *Moore v. Regents of the University of California* (51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479

Annas J,G. (1988): At Law: Whose Waste Is It Anyway? The Case of John Moore. The Hastings Center Report, Vol. 18, No. 5 (Oct. - Nov., 1988), pp. 37-39

Moore value in the body

The statement Moore was asked to sign within the consent form:

"I (do, do not) voluntarily grant to the University of California all rights I, or my heirs, may have in any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained from me"

'I give my tissue as an unconditional gift…' A common approach used in humans tissue research projects

Moore value in the body

Sign 'I do'

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Legal findings in Moore

- Moore had no property rights in his cells – spleen and other cells judged to be ‘mere raw’ materials transformed by the labour of the doctors/scientists
- Took naïve view that tissue would be distributed and shared for public good which Moore may restrict (but scientists took out a patent on the ‘Mo Line’)
- The only breach was in fiduciary duties (failure to obtain (sufficiently) informed consent.

Pressing issues in genomics research today – what are they?

- Long shadow of Nuremberg – is the model of research ethics appropriate for genomics research?
  - personal responsibility of researcher
  - What’s the duty of care of the researcher in ‘big data’ projects?
- Long shadow of ‘genetic determinism’ – elevated perception of risk by regulators, RECs/IRBs/ potential participants:
  - Predictive powers (late onset disease)
  - Behavioural traits
  - Family implications
- Human Genome Project – debates about genetic privacy and risk of discrimination resulting in Genetic Privacy Legislation

DeCode: Icelandic Biobank

- Public /Private Venture
- Unique opportunity: ‘genetic’ treasure trove
- Public (and private) benefit
- Government support
- Presumed Consent

But:

- Not universally popular
- Legal challenges
- deCode didn’t deliver
- Financial failure

- Other Examples
- Estonia
- UK Biobank
- 100k Genomes

Pressing issues in genomics research today – what are they?

- ☐ Legal uncertainties – changing data protection legislation, legal precedent, lobbying in different directions
- ☐ Changing social contexts – social media, normalisation of, and ‘willingness’ to relinquish privacy rights
- ☐ Snowden revelations – no such thing as privacy!!
- ☐ 23andMe – now under legislator’s gaze
- ☐ Technology out-pacing regulation

NHANES III: National Health and Nutrition Examination Survey (1988-94)

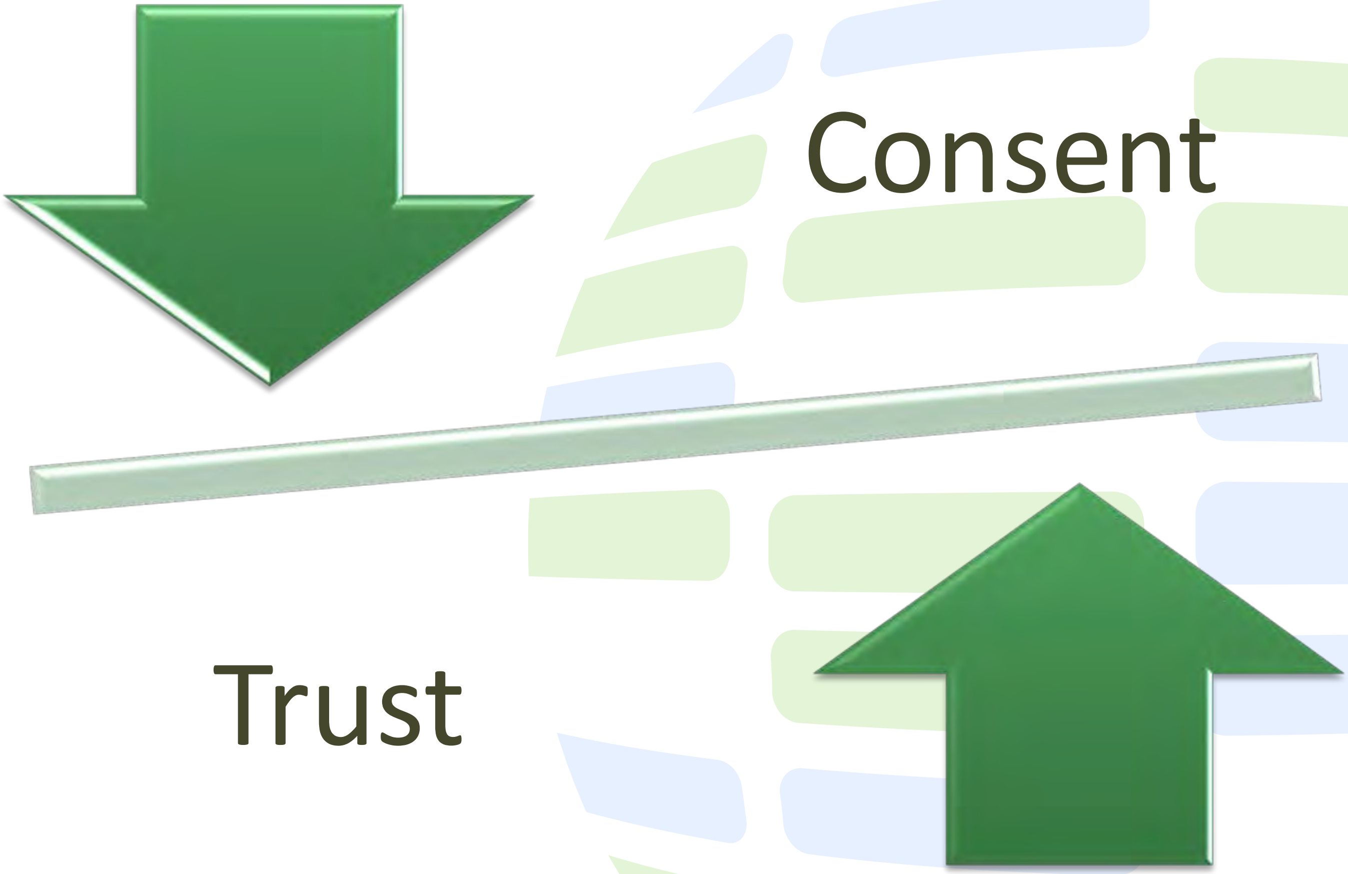
- Longitudinal study of health and nutrition of the general population (adults and children)
- Linked personal medical data with samples
- Consent:
- “A small sample of your blood will be kept in long-term storage for future testing”
- In the light of new genetic research possibilities was the consent adequate?
- Cost of re-consent

Consent

- **Blanket or Open Consent:** acknowledges the uncertainty and open-endedness of genetic data research
- The Estonian Genome Project: consent for samples “the use thereof for genetic research, public health research, and statistical and other purposes in accordance with the law”

- **Limited/ restricted consent**: acknowledges potential risks to individuals/ collectives and gives greater autonomy to them
- *Arizona Board of Regents v. Havasupai Tribe 2010*
- USA Genetic Information Non-discrimination Act 2008

Consent



Consent

Trust

Consent

- Individual research participant/ family or community participation? (autonomy vs solidarity)
- Trust and responsibility – justified trust/ integrity
- Dynamic consent with multiple options at different levels – is this feasible in big data projects?
- Different models – Public Health – where approaches can’t easily be tailored to individual preferences
- Consultation, transparency, willingness to re-evaluate and revise

Confidentiality/privacy

- Underlying ethical reasons to respect confidentiality – respect for persons (also reflected in different forms of legal protection)
- Confidentiality relates to specific relationships and is created by the character of the relationship e.g. Doctor patient relationships (professional sanctions and legal remedies for breach of confidentiality)
- Privacy relates to a much broader and fundamental principle (related to autonomy and self-determination) – the right to have control (also underpinned by law – right to family and private life (ECHR)

Secondary use of data/ data sharing

- Tension between privacy and potential benefit
- Worthwhile goals – sharing for what purpose?
- Strategies at the outset of research – engineer data sharing into the project:
  - Consent (informed)
  - Anonymisation
- Security of data: trust and integrity again
- Sharing with whom? Who decides?
  - Internal governance structure
  - Commitment to wide sharing compatible with original aims
  - Commercial interests (Henrietta Lacks, Moore vs Regents of Univ. California)

Results and incidental findings

- General consensus that the results of research should be made available to participants (and the wider public) – principles of respect, solidarity, responsibility.
- Knoppers and Kharaboyan (2009) have argued that research participants are generally made aware that infrastructures for research are not the equivalent of health care or clinical trials; that participants generally know that they might receive public communication of generalised results from research but that they will not receive individualised results, including IFs

Results and incidental findings

- There is no consensus on the duties of researchers with regard to IFs
- There is no neutral starting point
- Ought implies can – structural systems to manage obligations
- Article 27 – Duty of care: If research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information (Oviedo 2005)

3 Ethical Questions

- **Who are you trusting and with what?**
- **What are the risks?**
- **What are the safeguards?**
    - Consent
    - Confidentiality and privacy
    - Redress
    - Withdrawal
- **What is the cost of ‘high safety’ strategies**
- **Solidarity**: What is in it for me? What is in it for others?

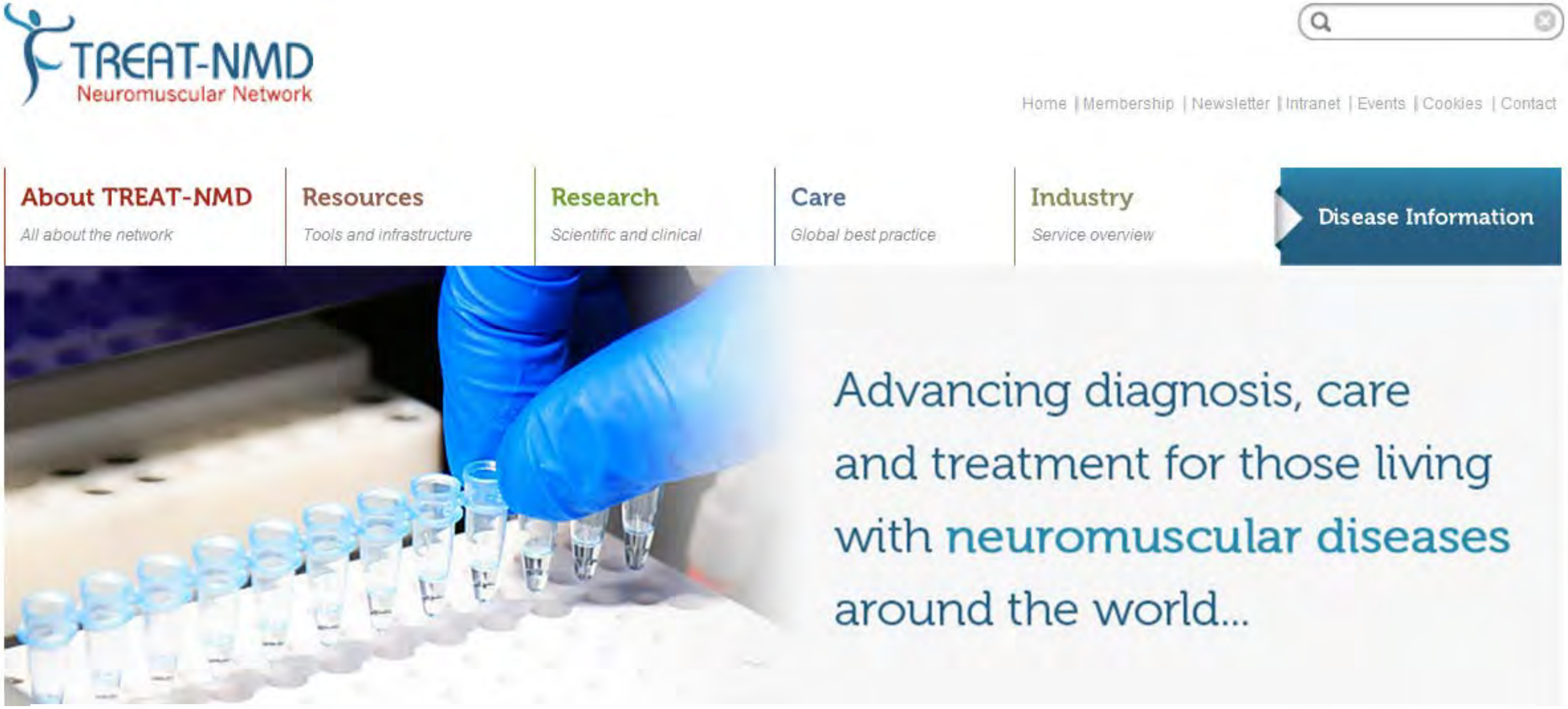
Collaborations: Rare Genetic Disease

- ☐ IRDIRC: two main objectives by the year 2020
  - deliver 200 new therapies for rare diseases
  - means to diagnose most rare diseases.
- ☐ Creating a Global Alliance to Enable Responsible Sharing of Genomic and Clinical Data June 3, 2013
- ☐ http://www.ebi.ac.uk/sites/ebi.ac.uk/files/shared/images/News/Global_Alliance_White_Paper_3_June_2013.pdf

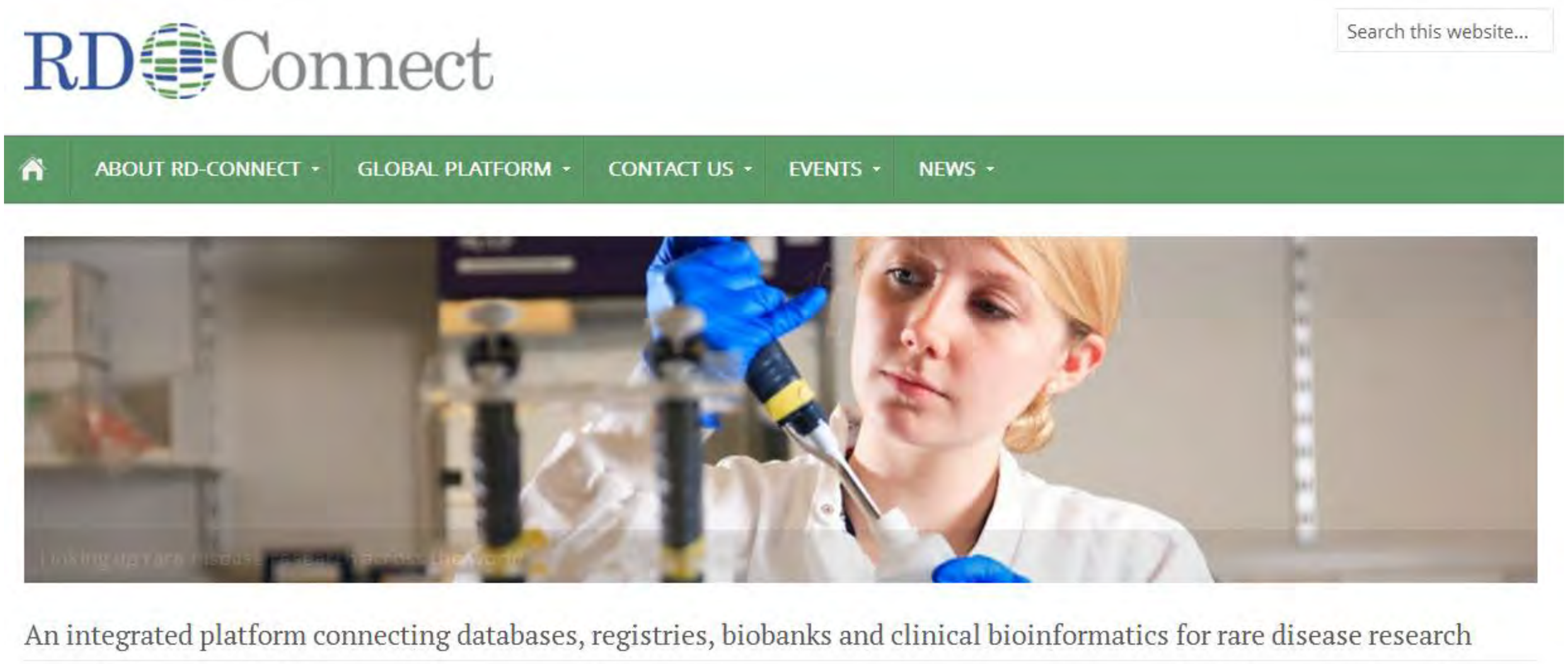
Global Alliance
for Genomics & Health

The Voice of Rare Disease Patients in Europe

IRDiRC
INTERNATIONAL
RARE DISEASES RESEARCH
CONSORTIUM



Advancing diagnosis, care and treatment for those living with **neuromuscular diseases** around the world...



Linking up rare disease research across the world

An integrated platform connecting databases, registries, biobanks and clinical bioinformatics for rare disease research

Questions?

26 May 2014

References

- Association of British Pharmaceutical Industry (ABPI) Guidelines on the secondary use of data for medical research purposes. (London 2007)
  - Big data road map (London 2013)
- Boddington P. (2012) Ethical Challenges in genomics Research. Springer. London.
- Johnstone C and Kaye J. Does UK Biobank have a legal obligation to feedback individual findings to participants? Medical Law Review 2004.12: 239-67Clayton EW. Incidental findings in genetics research using archived DNA. J Law Med Ethics 2008. 36: 286-91
- Knoppers BM and Kharaboyan L. 'Deconstructing' Biobank communication of results 2009 6:3 SCRIPTed 677, http://www.law.ed.ac.uk/ahrc/script-ed/vol6-3/knoppers.asp
- O'Neill. Symposium on consent and confidentiality: Some limits of informed consent. J Med Ethics 2003;29:1 4-7 doi:10.1136/jme.29.1.4
- Prainsack, B. and Buyx, A. (2011). Solidarity: Reflections on an Emerging Concept in Bioethics. London: Nuffield Council on Bioethics.
- Mello MM, Wolf LE. The Havasupai Indian tribe case–lessons for research involving stored biologic samples. N Engl J Med 2010;363(3):204-207.

Acknowledgements/collaborations

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