

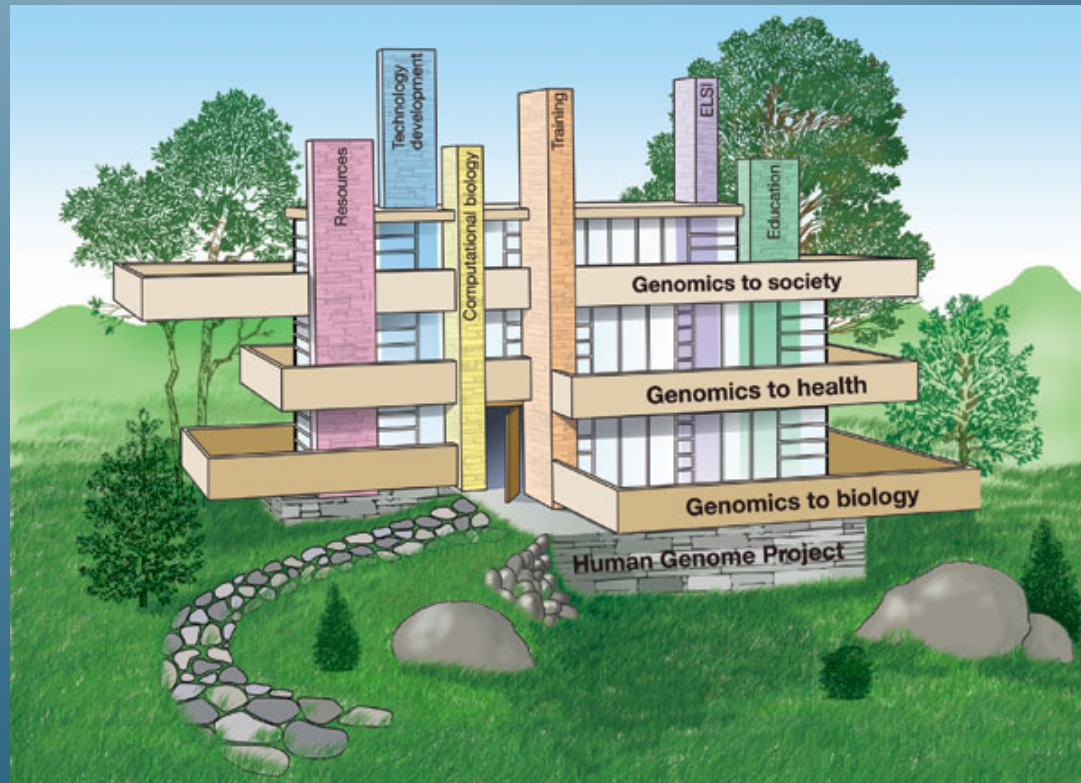
OPEN BIOTECHNOLOGY: Capitalizing on the Human Genome?



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Outline

- Introduction and Terminology
- The Open Biotechnology Community
- Benefits
- Challenges
- Conclusion



Introduction and Terminology

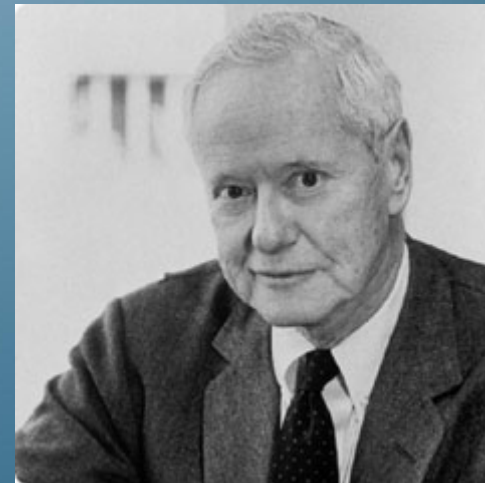
Then after divers meetings and consults of our whole number, to consider of the former labors and collections, we have three that take care out of them to direct new experiments, of a higher light, more penetrating into nature than the former. These we call lamps. Francis Bacon, New Atlantis



Introduction and Terminology

The Norms of Science (Robert K. Merton)

- Communalism
- Universalism
- Disinterestedness
- Organised Scepticism



Introduction and Terminology

The Open Source "Revolution"

You see, the purpose of science and technology is to develop useful information for humanity to help people live their lives better. If we promise to withhold that information—if we keep it secret—then we are betraying the mission of our field.

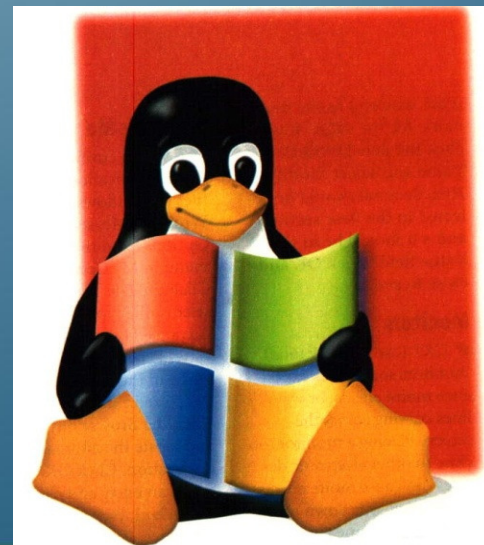
Richard Stallman, Free Software, Free Society (2004)



Introduction and Terminology

Open source is a development method for software that harnesses the power of distributed peer review and transparency of process.

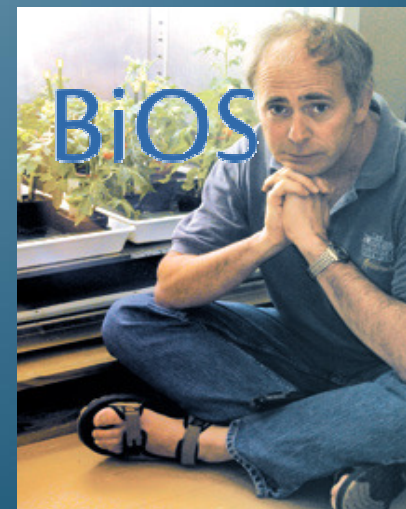
FSF → Open Source Initiative → FLOSS



Introduction and Terminology

- *To the shared dismay of both scientists and thoughtful citizens, patent systems and the myriad gaming practices they have spawned today are impeding innovation as a social enterprise, and continuing to deprive most of the world's population of such fundamentals as adequate nutrition, access to health care services, and clean water.*

Richard Jefferson, *Science as a Social Enterprise innovations*, fall 2006

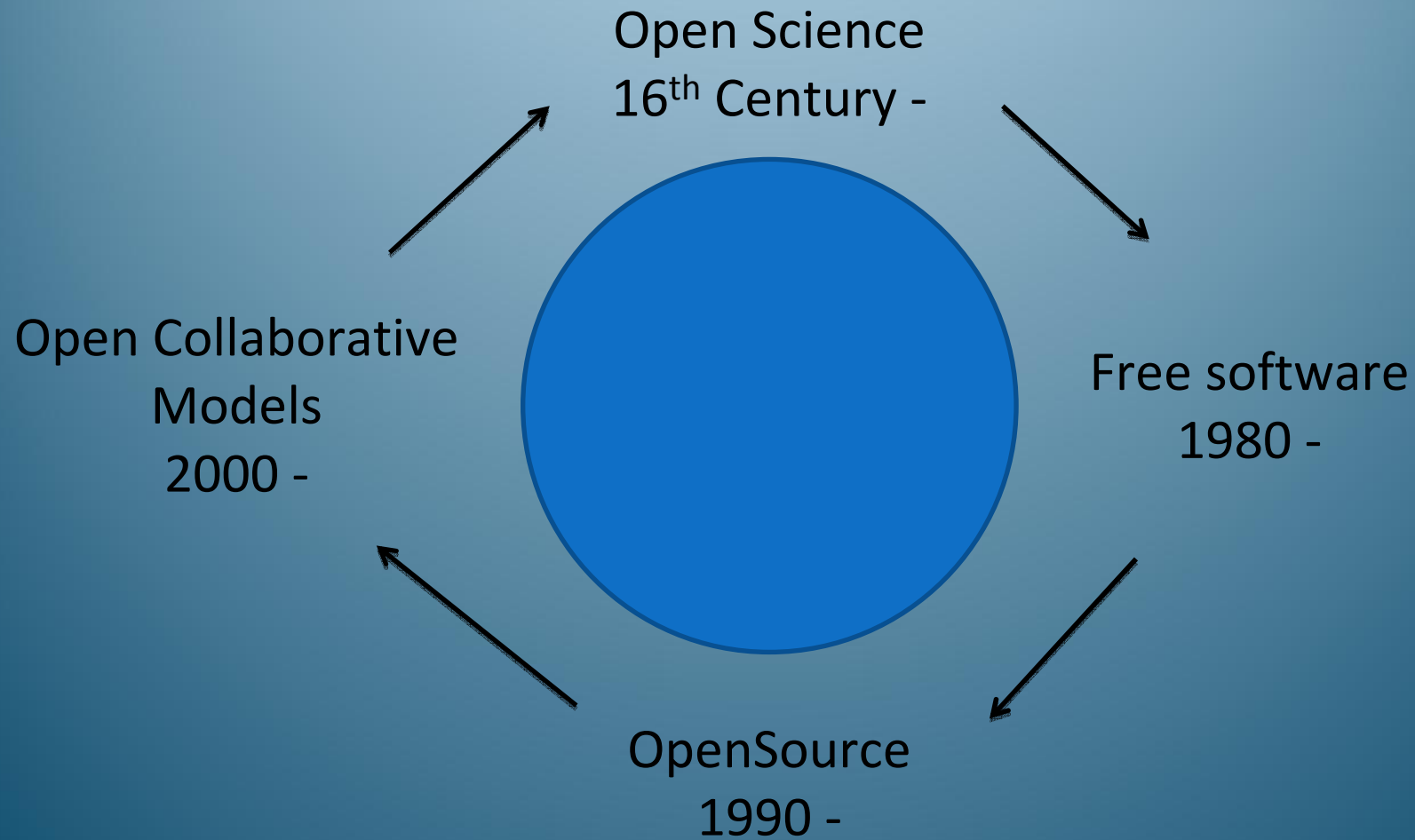


Introduction and Terminology

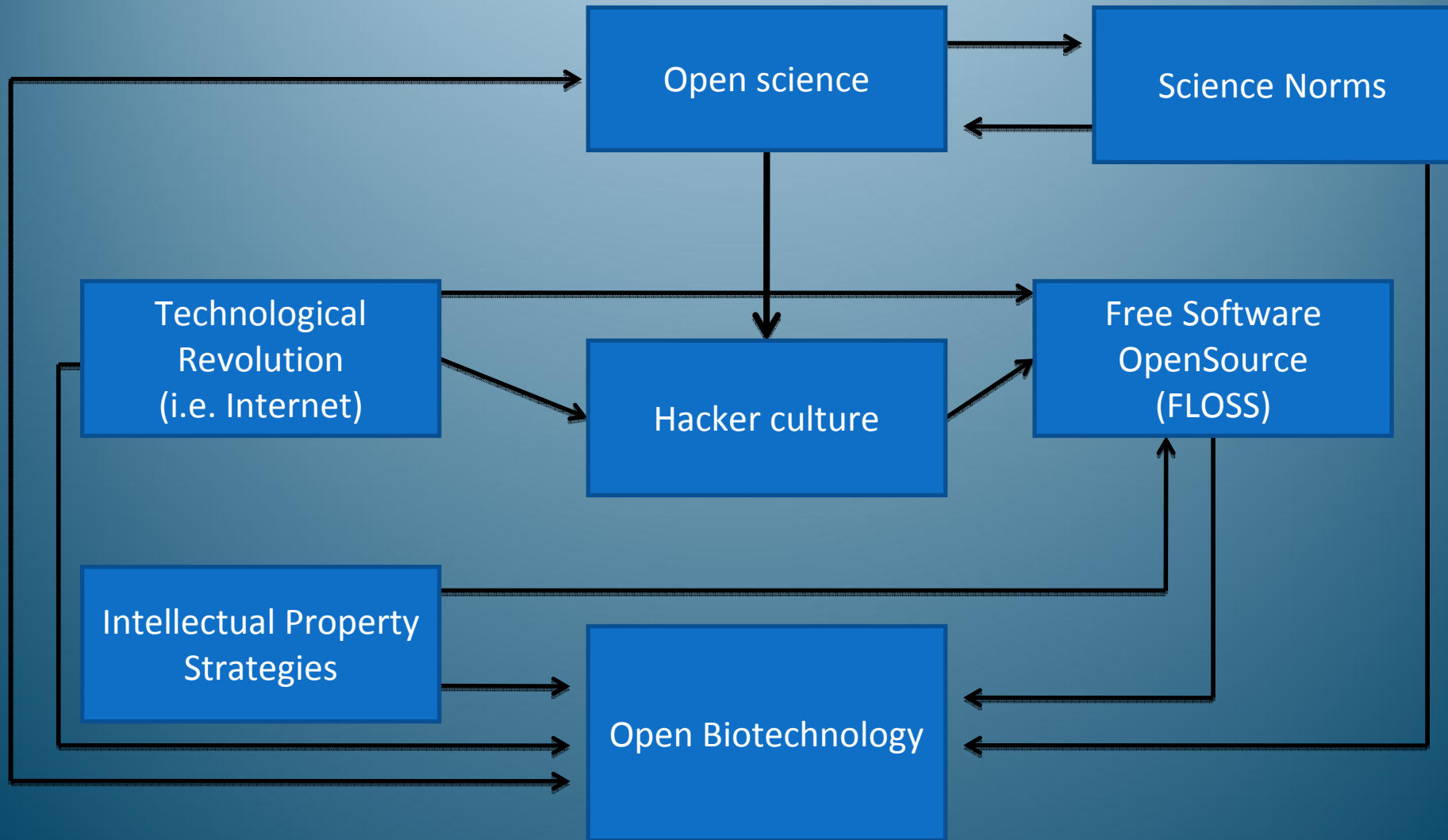
1. Make use at one stage or another of the internet and other information technologies.
2. Design in a way that will permit other members of the scientific community to collaborate on the project.
3. Include a strategy to ensure rapid public dissemination of the information and research results.
4. Permit members of the scientific community to use results without having to conclude restrictive agreements that would limit research freedom and integrity.
5. Not use intellectual property (IP) to limit access to the project, its results or to discriminate between different uses or different users.

Yann Joly, "Open Biotechnology: Licences Needed" (2010) Nature Biotechnology

Open approaches (1)



Open approaches (2)



Industrial society



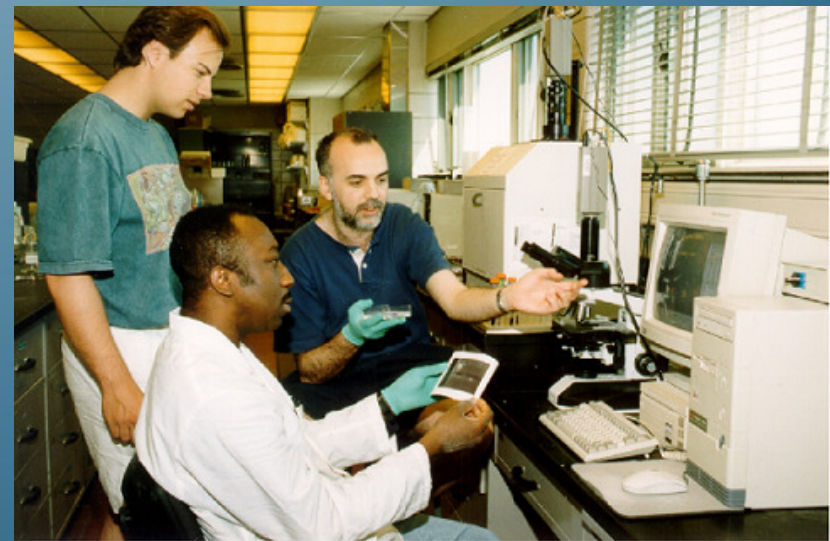
Information society

The Open Biotechnology Community

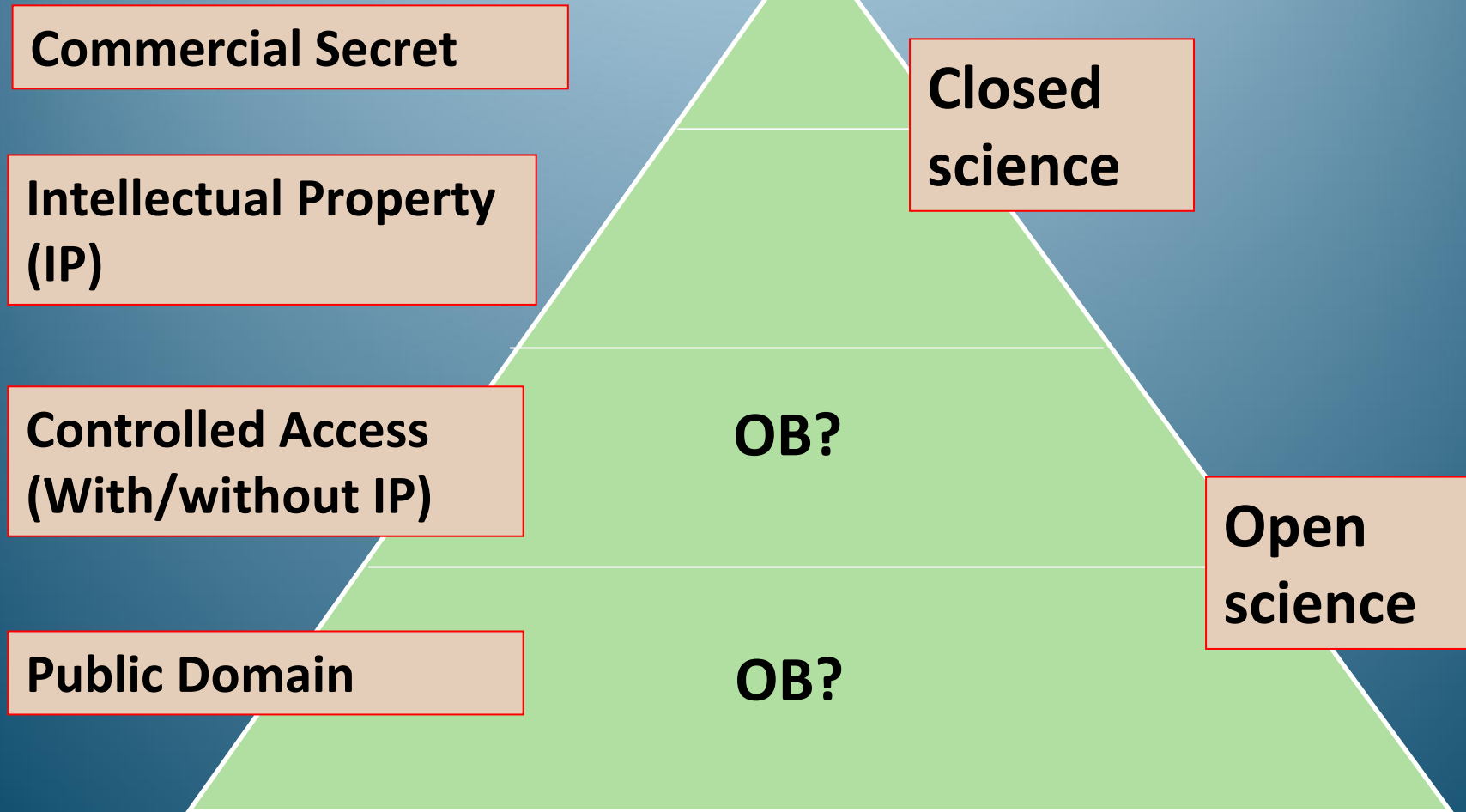
- (1996) *Bermuda Principles*
- (2000) *Clinton-Blair Joint Statement*
- (2003) Wellcome Trust, *Ft. Lauderdale Agreement*
- (2005) Foundation of the BIOS initiative
- (2007) Science Common, *Protocol for implementing Open Access Data*
- (2009) *Federal Research Public Access Act of 2009*

The Open Biotechnology Community

- Scientific publications
- Bioinformatic softwares
- Genomic databases
- Wet laboratory
- All of the above



Is your project open?



Benefits

- Promote interoperability and harmonization of platforms and tools for genomic research.
- Improve transparency and peer review of published research.
- Lower the level of financial risk in genomic research.
- Avoid duplication of research projects.
- Democratize access to genetic research and innovation.
- Increase the performance of the patent system in the field of biotechnology?
- Provide a more sustainable technology transfer strategy?
- Compatible with the ethos of the scientific community.

Challenges

- Spark the interest of the private sector and generate revenues.
- Develop simple, efficient and legally valid OB licenses.
- Create an incentive/reward system to ensure optimal participation from scientists in the public sector.
- Harmonize OB practices and develop central governance structure(s).
- Demonstrate the relevance of OB for "wet lab" projects and integrated projects.
- Reconcile OB philosophy with research ethics (informed consent, confidentiality).
- Enforce access policies and licenses.
- Model is difficult to sustain in small research projects?

Challenges

A conflict of values ?

- Confidentiality, consent = individualism (autonomy, privacy)
- Open science = solidarity (collaboration, transparency)



Challenges

Informed consent

- Disregarding consent-related limitations in the sharing of data is unethical as it violates both the right to confidentiality and the right to integrity of research participants.
- The need to openly share data should be considered by researchers and research sponsors from the very onset of a research project.
- A minimum amount of information on future uses of data must be provided in the consent form.

Challenges

Confidentiality

- *If someone has access to individual genetic data and performs matches to public SNP data, a small set of SNPs can lead to successful matching and identification of the individual.*

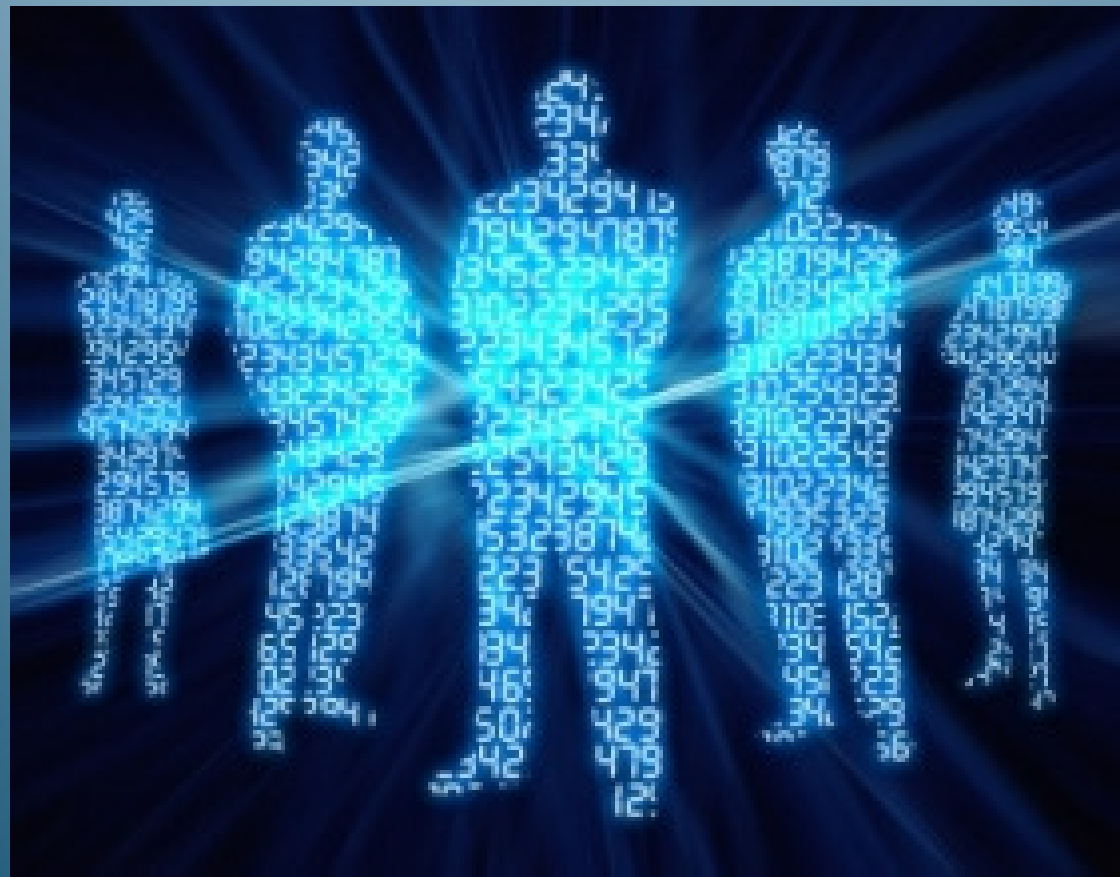
Lin, Owen, Altman, *Science* (2004)

- *It is possible, in principle, to identify an individual's genomic data within a large dataset of pooled genomic data.*

Homer et al., *PLoS Genetics* (2008)

Challenges

Confidentiality



Challenges

1000 Genomes Project

- *Although [w]e will take many measures to protect your privacy, we will generate lots of genetic information about each person whose sample is studied. This information will be put in open access scientific databases, available on the Internet to anyone who wants to look at it. [A]s technology advances, there may be new ways of linking information back to you that we cannot foresee now [...]. We believe that the benefits of learning more about human genetic variation and how it relates to health and disease outweigh the current and potential future risks [...].*

Challenges

Prepublication Data Sharing/ *Toronto Statement (2009)*

- For aggregated data that cannot be used to identify individuals, databases are open access, but for clinical and genomic data that are associated with a unique, but not directly identifiable individual, access may be restricted.

Nature 461, 168-170 (2009)

Open Licences

- Needed: simple, efficient, legally valid licences.
- Alternatives: patent pool (or clearinghouse), public domain, non-assertion covenants.

- Legal precedents:

- *Curry v. Audax*, (2006) USA
- *Jacobsen v. Katzer* (2008) Netherlands
- *Susan Chang et al. v. Virgin Mobile* (2009)



Enforcing Open Source

- Social sanctions:
 - Withdraw all access privileges
 - Refuse publications
 - Impact on future collaborations with peers
- Legal sanctions
 - Liability suit
 - Injunction

Enforcing open source

Paper Retracted Following Genome Data Breach



Scooped. Another team broke the database embargo and published a paper using Laura Bierut's data.

Constance Holden, Science, 2009

Enforcing Open Source

Paper Retracted Following Genome Data Breach

➤ Actions taken:

- Yale took down a press release it had posted about the study.
- NIH froze the researchers' access to dbGaP.
- PNAS retracted the paper from its print edition and added a retraction notice to the online edition.

Conclusion

