

Internationalization Working Group

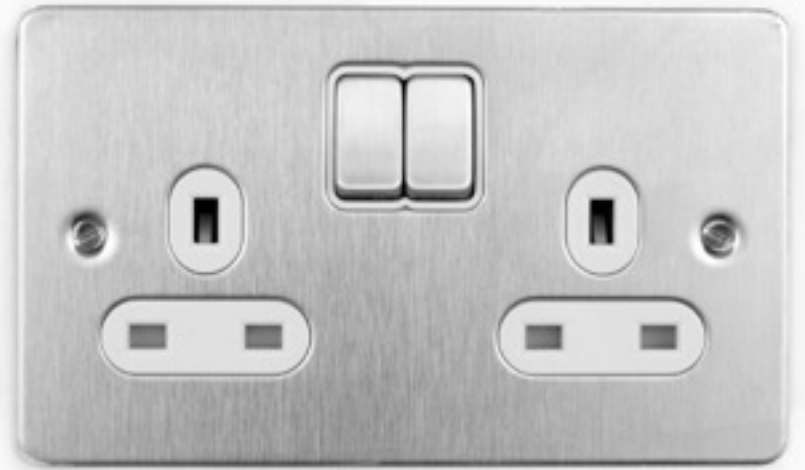


Friday, April 23, 2010

enormous potential asset to the international community.

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but...







the law
the contracts
the institutions
human genomic privacy

Mission:

understand, design, and
recommend.



a series of interviews

Key Themes Regarding International Data Collection and Distribution

1

the constraints created by the use of human subjects as the source of data.

Eg.:

- individual's right to privacy,
- anonymity to the obligations posed by IRBs,
- different rules developed and developing nations,
- necessity to observe strict regulations and pre-existing clinical study designs

2

complex set of relationships between scientists and institutions across national boundaries

Eg.:

- the national policies that govern some scientists,
- competitive instinct,
- negotiating leverage,
- perceptions of potential to exploit human subjects by scientists in the developed world.

3

complex data sharing projects are governed by multiple principles, ranging from the ethical to the legal and scientific

Eg.:

- orthogonal problems with data interoperability and usability

Success Lessons:

- formal but lightweight process using standardized, pre-negotiated terms and documents creating a paper trail of ownership, responsibility, and confirmation.

4

the potential for unexpected problems

Eg.:

- Use of Clinical data and public health data, used as weapons if those data have negative economic externalities

Recommendations given:

- Hub-and-spoke privacy networks
- Genetic non-discrimination legislation

5

importance of clear marking of rights associated with data – a transparency and certainty problem

Conclusions

1. International scientific research is “normally” complex.
2. Norms and contracts and IP and privacy combine.
3. Standards appear to be the most promising solution.
4. Use a specific case to drive the general.



We want :

- to perform more (and you will be asked to contribute later in the Internationalization breakout session);
- to engage key individuals and institutions to assist the Sage Commons going forward on international issues;
- expect the questionnaire to re-emerge after additional consultation and research with the community;
- call on interested parties to annotate this document with experiences, solutions, and new ideas.