Time for a re-set on HUMAN <> research protections

IOM Workshop on Contemporary Issues
in Human Research Protections
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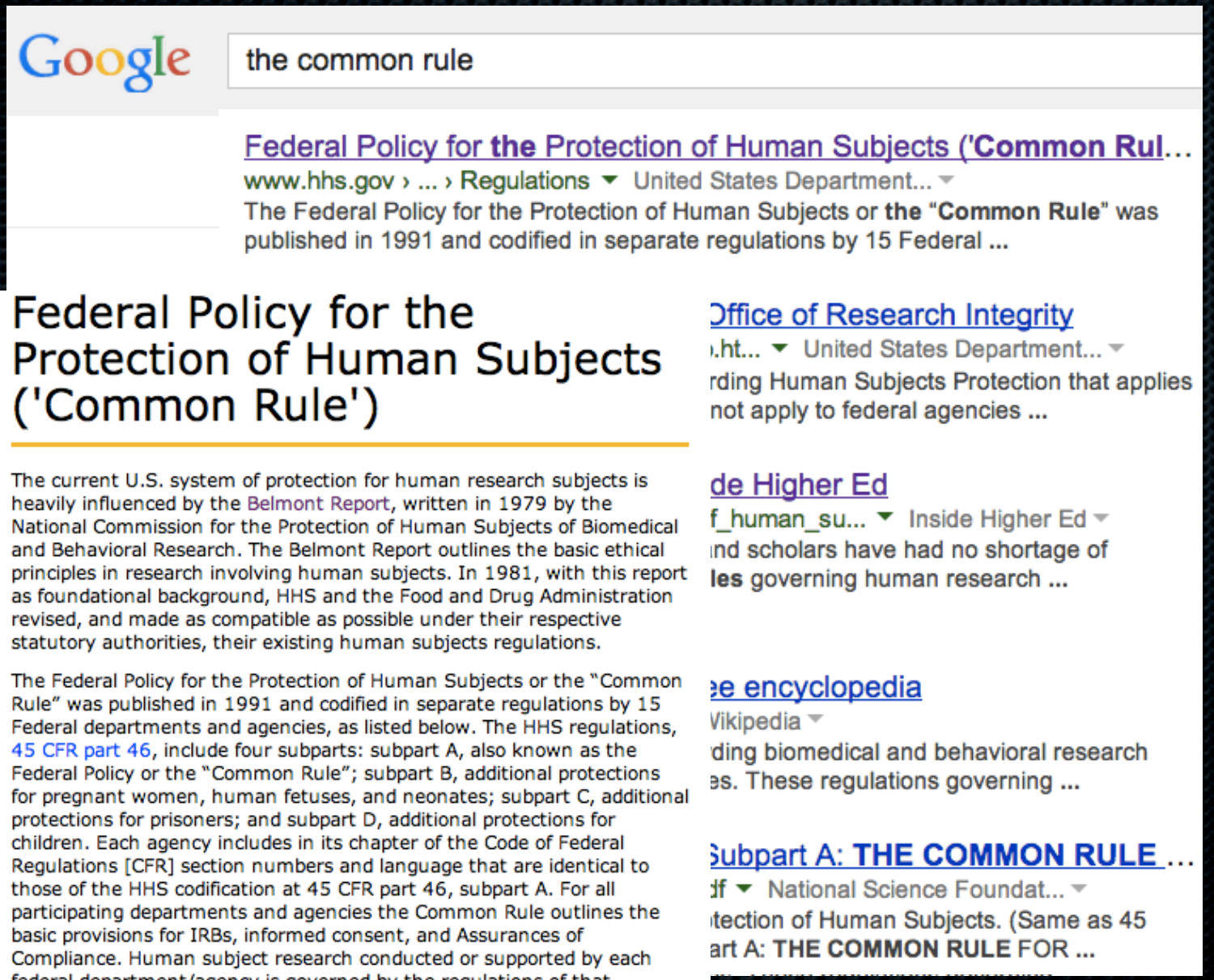
How do we talk about research protections?

What's happened in 20 years?

- Google conquered the world
  - Already in & out of health marketplace
- Mobile tools
  - Communication + Medical
- Cancer: more complicated
  - Data + biospecimens
  - Clinical trials
  - Informed consents
- The Common Rule?
  - Google it



How many informed consent re-dos?

- Personally involved in 5+ national ‘fix it’ committees
- Regulations
  - Interpretations?
  - Policies?
- How many IRBs (& committees)?
  - Policies?
  - Tweaks?
  - Interpretations?

REALITY: a risk contract

MEDICINE

Informed consent on trial

Lengthy, complicated documents leave many clinical-trial participants in the dark about the risks they face.

"An influential group of ethicists and researchers warned ... that the process has become a box-ticking exercise focused **more on offering legal protection to a trial's organizer than actually protecting patients.**"

Nature, volume 482, 2-2-2012, p. 16

- Who's risk?
- Patients as liabilities?
- Result:

CoverYourAspirations

Words Matter

SUBJECT

Lab rat?

Against my will?

Both?

Worse?

(to a) Human in a research study

Words Matter

Patients consider it a noun AND a **verb**!

SUBJECT

Lab rat?

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Words Matter

CONSENT

Sign to get medical care
-or-
what they’ ll do to me

A form that complies with federal regs

Series of band-aids

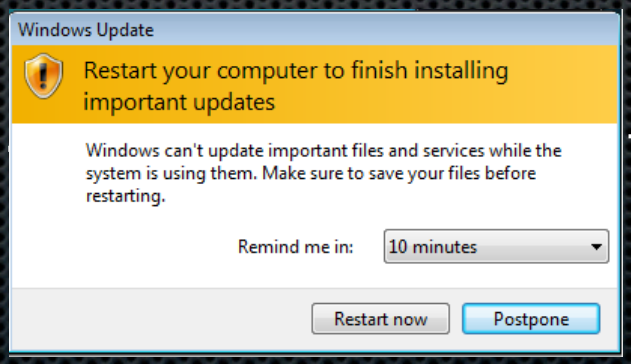
Lots of tweaks

- HIPAA is a problem to all[1]
- Common Rule/ANPRM
- NCI common consent
- GBC consent + IRB sheet + patient brochure
- Re-consenting for…
- Genome interpretations[2]
- Quality of Informed Consent measurements[3]

Need fundamental change

[1]Ness RB. JAMA. 2007;298(18):2164-2170.
[2]Peppercorn J et al. Cancer. 2012 Oct 15;118(20):5060-8
[3]Joffe S et al. J Natl Cancer Inst. 2001 Jan 17;93(2): 139-47

Let’s get REAL

- Research system is regulatory-focused, not patient-focused
  - Stop saying informed consent is for patients, then write them for institutions & industry
- Patients don’t want the pill, treatment or intervention
  - They want the RESULT
- Time to  the system!

An artificial separation?

- Research v. care
  - Created by penal policy (reactionary)
    - Concerns are valid
  - Created fearful environment
  - Individual results sought by people
  - Data sharing wanted, but regulations thwart

What are we really trying to accomplish?

The C words

- Useful COMMUNICATION
- In CONTEXT for each audience (stakeholder)
- How?
- **Changing CULTURE from regulatory to PATIENT**
  - Parallel actions needed
  - Communication skills/tools (education)
    + change in regulations
- Time to think strategically (focus on future)

Patient views of informed consent

- Want a path to follow that fits THEIR lives
- Is this therapeutic misconception?
- IRB inconsistency
  - Patients don’t have equal access
  - What is ethical about that?
- Patients will want to re-identify when new diagnostics or treatments appear

Change the APPROACH, not just the form

Separate opposing concepts

Patients:

Trials are part of their life story

- Explain them that way
- People need context & will hope anyway

Institutions/industry:

OK if you're up front about it

- Don't pretend it's for the patient's benefit
- Handle separately

Change the APPROACH, not just the form

Do we need all of these pieces ‘as is’?

- Common Rule, HIPAA, FDA, OHRP, OCR, IRBs, etc.

Show respect for people with words used

- No more “subjects” who must “subject” to research
- You don’t partner with your subjects

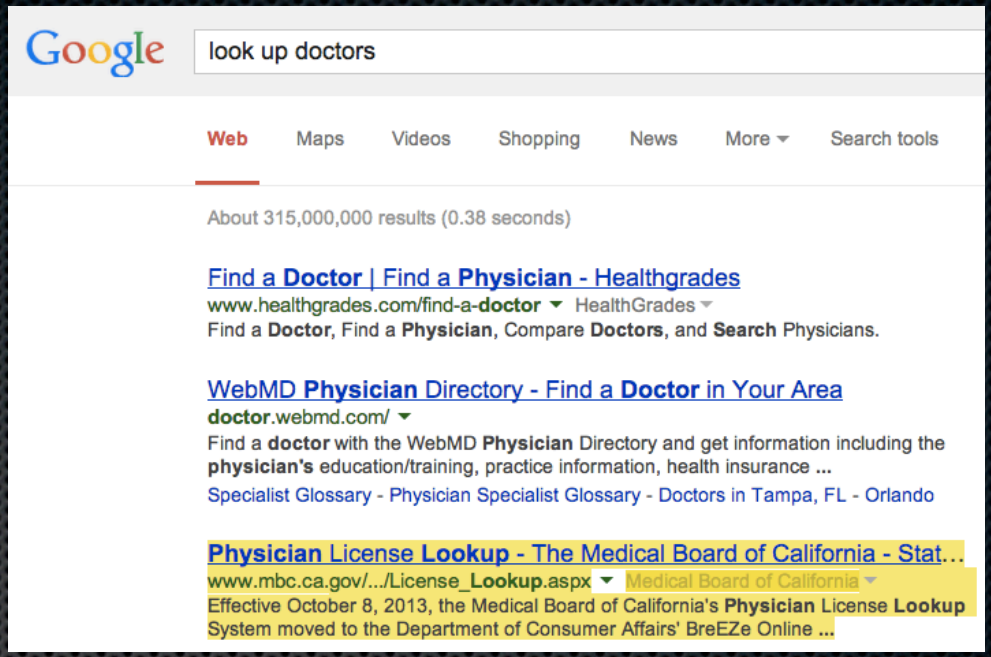
Change the APPROACH, not just the form

It’s not 1974

It’s not 1991

In 2014…

- Social media, clouds
- Mobile devices
- Virtual networks, online news/forums
- Multi-sensory, not paper
- Online forever…
  - Facebook for people who die
  - Perpetual avatar



What if there were no IRBs tomorrow?

- Absurd?
  - No more conflicting committees across & within institutions
- In 2014, how would we address…
  - Uncertainty?
  - Accountability?
  - Transparency?
  - Health literacy?
  - Accelerated/breakthrough status?

Possible perceptions to consider

- Driver's license donor program
- Credit bureaus
- Amazon/Facebook/Google
- NSA

- Neither good nor bad, but what are the connotations?
- Time for strategies before potholes appear

Universal research consent?

Not new*

- BMJ (2003), UChicago (2003), AAMC (2007), AMA (2011), WHO, Sage Bionetworks (2012)
- Trials, registries, biobanks, outcomes, surveys, etc.

More complications, more need

Already moving in this direction, so why resist?

- What if there was/is a consent app?

* References at end of presentation

If you decide to stay in your box…

- Critical concepts: partnership, respect & trust
- Build multiple models
- Feedback loops from all
- Continually adapt

- Stop doing it WRONG!

The New York Times

Science

I Had My DNA Picture Taken, With Varying Results

Ozier Muhammad/The New York Times

Kira Peikoff, 28, had her DNA tested by three direct-to-consumer companies, and the results didn't agree.

By KIRA PEIKOFF

Published: December 30, 2013 | 421 Comments

Thanks for all you do for patients and their families

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References for universal consent slide

- BMJ/NEJM:
  - http://www.ncbi.nlm.nih.gov/pubmed/15070791
  - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC411155/
  - http://www.ncbi.nlm.nih.gov/pubmed/15295059
- U Chicago
  - http://www.uchospitals.edu/news/2003/20030415-informed-consent.html
- AAMC
  - https://www.aamc.org/download/75282/data/hdicklermtgsumrpt53007.pdf
- AMA
  - http://www.ama-assn.org/resources/doc/ethics/ceja-6a11.pdf
- WHO
  - http://www.who.int/rpc/research_ethics/informed_consent/en/
- SAGE Bionetwork
  - http://sagebase.org/platforms-and-services/portable-legal-consent/