

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

[Federal Policy for the Protection of Human Subjects \('Common Rule'...](#)[www.hhs.gov](#) > ... > [Regulations](#) ▼ [United States Department...](#) ▼

The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal ...

About OHRP**Regulations**Human Subjects
Research (45 CFR 46)Food & Drug
Administration**Common Rule****Policy & Guidance****IRBs & Assurances****International****Compliance Oversight****Education****Advisory Committee
(SACHRP)****News Room****Archived Materials****Contact OHRP**

Federal Policy for the Protection of Human Subjects ('Common Rule')

The current U.S. system of protection for human research subjects is heavily influenced by the [Belmont Report](#), written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report outlines the basic ethical principles in research involving human subjects. In 1981, with this report as foundational background, HHS and the Food and Drug Administration revised, and made as compatible as possible under their respective statutory authorities, their existing human subjects regulations.

The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies, as listed below. The HHS regulations, [45 CFR part 46](#), include four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. Each agency includes in its chapter of the Code of Federal Regulations [CFR] section numbers and language that are identical to those of the HHS codification at 45 CFR part 46, subpart A. For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. Human subject research conducted or supported by each federal department/agency is governed by the regulations of that department/agency. The head of that department/agency retains final judgment as to whether a particular activity it conducts or supports is covered by the Common Rule. If an institution seeks guidance on implementation of the Common Rule and other applicable federal regulations, the institution should contact the department/agency conducting or supporting the research.

[Office of Research Integrity](#)[.ht...](#) ▼ [United States Department...](#) ▼

rding Human Subjects Protection that applies not apply to federal agencies ...

[de Higher Ed](#)[f_human_su...](#) ▼ [Inside Higher Ed](#) ▼

ind scholars have had no shortage of les governing human research ...

[e encyclopedia](#)[Wikipedia](#) ▼

ding biomedical and behavioral research es. These regulations governing ...

[Subpart A: THE COMMON RULE ...](#)[Jf](#) ▼ [National Science Foundat...](#) ▼

tection of Human Subjects. (Same as 45 art A: THE COMMON RULE FOR ...

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?

Both?

Against my will?

Worse?

(to a) Human in a research study

Words Matter

Patients consider it a noun
AND a verb!

Lab rat?

Both?

Against my will?

Worse?

(to a) Human in a research study

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 all¹
- Common Rule/ANPRM
- NCI common consent
- GBC consent + IRB sheet + patient brochure
- Re-consenting for...
- Genome interpretations²
- Quality of Informed Consent measurements³

Need fundamental change



¹Ness RB. JAMA. 2007;298(18):2164-2170.

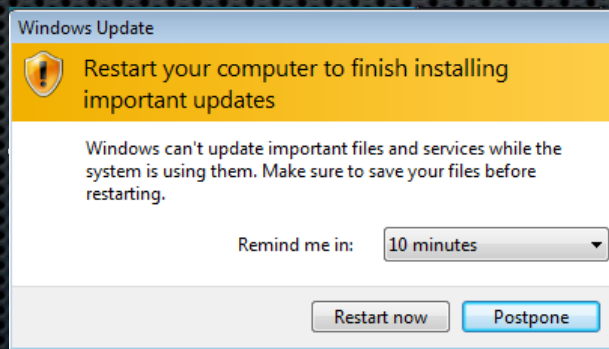
²Peppercom J et al. Cancer. 2012 Oct 15;118(20):5060-8

³Joffe 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

Institutions/industry:

OK if you're up front about it

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

Patients:

Trials are part of their life story

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



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

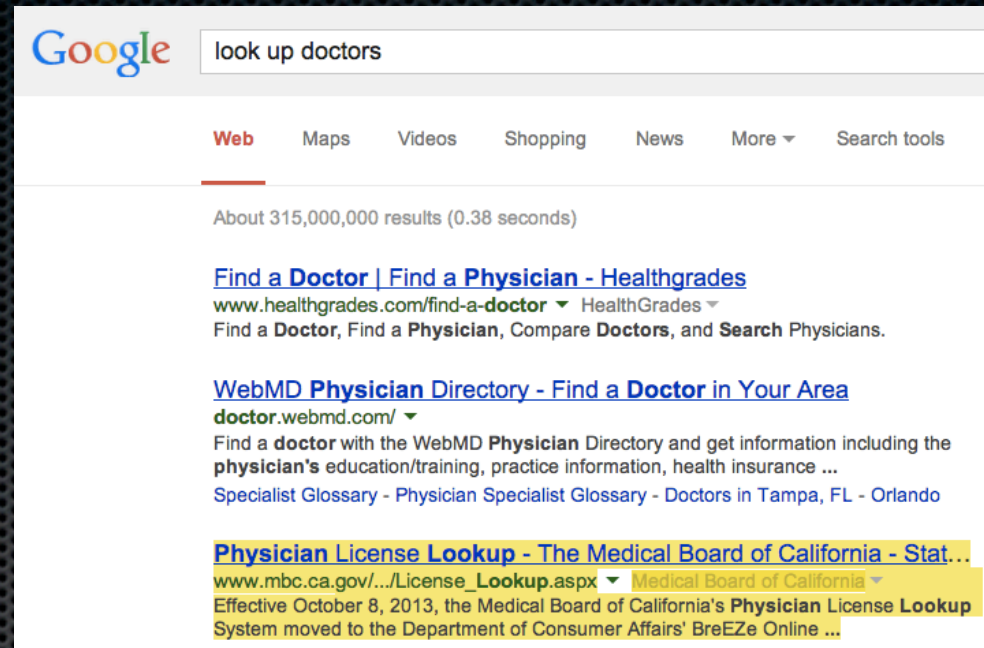


It's not 1991



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!

Sequenced cDNA Clones

From \$9

Sino Biological Inc.
Biological Solution Specialist

Full length/Various species/sequence

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>
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 - <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/>