

Research Ethics and safety: Inconvenient truths

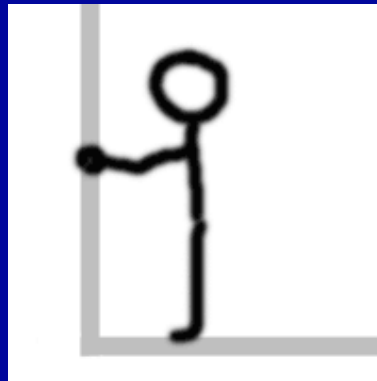
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A Failure to Communicate?

A production of
ETHICS ANONYMOUS™



More Regulation, Training?

Absolutely no reason (much less evidence) to think more regulation has improved safety, or that more regulation will do so in the future.

*"If you have ten thousand regulations
you destroy all respect for the law."*

- Winston Churchill

In the beginning

KISS: Keep it simple, Stupid

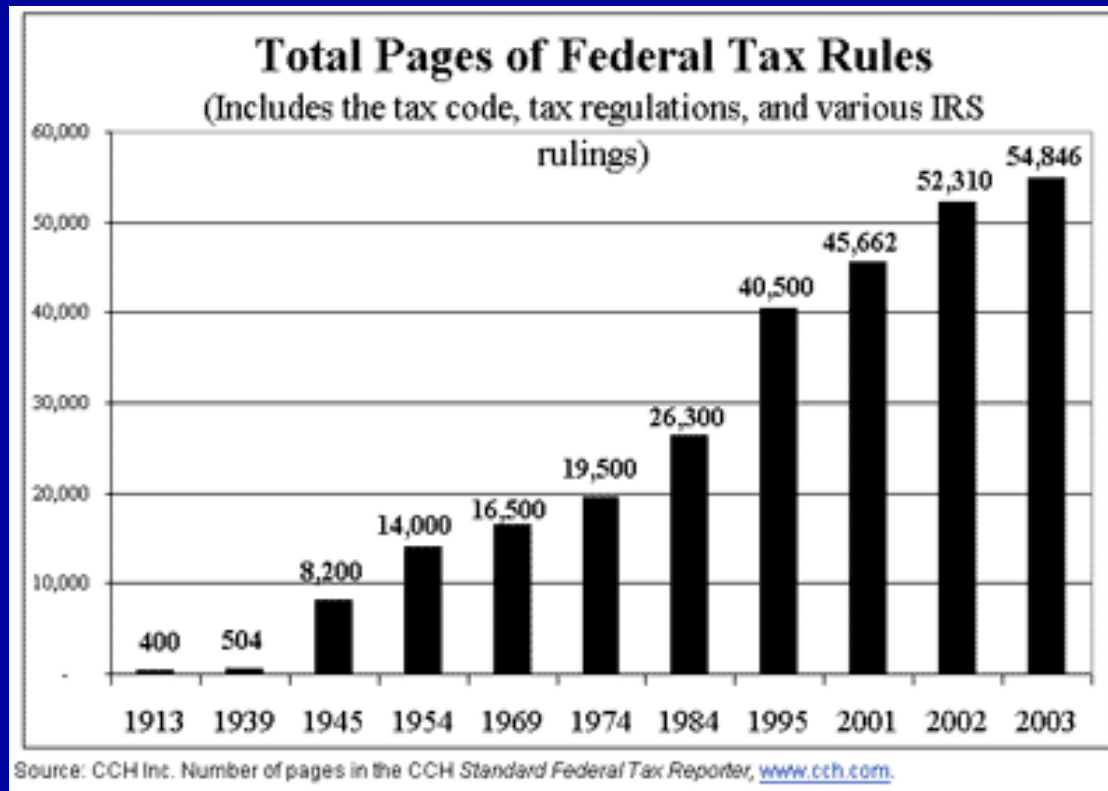
- The Golden Rule: eleven words
- Ten Commandments: about 135 words
- Oath of Hippocrates: 224 words
(or 3 words: “Do no harm”?)

Research Ethics

- USA: 45-CFR-46, + + +
- Plus local "interpretations," workshops, etc.
- Plus Helsinki, Belmont, +++

?? words

US Tax Law *(2006 = 66,000 pages)*



We could simplify here too, “10% apiece”, 2 words?

Tax Codes

IRS (USA):

- A tax code that is six times longer than "War and Peace"
- Plus 8 million words — 20,000 pages — of regulations
- A gazillion words of Guides for Dummies
- Forms-R-Us™ -- create that paper trail
- JOBS, JOBS, JOBS: lawyers, accountants, etc.

Ditto for IRBs

Federal Ethics

Word count: more numerous than grains of sand.

More regulations just mean more “gotchas”, not “higher” ethics.

Adversarial, least-effort climate.

(Churchill ... With enough laws, we all become criminals)

More Resources?

Example: Northwestern University Office for the Protection of Research Subjects "grew from two full-time professionals in the late 1990s to 25 professionals and an administrative staff of 20 last year (2005)." Not to mention departmental-level resources.

How much is enough? Why more, if no evidence?

JOBBS, JOBBS, JOBBS: Vested interests on-campus, even more off-campus, especially in the medical areas. At 30+ years, some have spent an entire career at this, with no evidence of benefit.

Has a regulatory agency ever shrunk, much less disappeared?

Never-ending "Creep"

- Safety -- OK
- "Ethics" -- poorly defined
- "Responsible" -- poorly defined

- Ethics committees "trump" ... In research, data trumps?

- Freedom of inquiry keeps falling down the list

"Creep" just names it, doesn't explain or resolve anything.

Why?

- Early (late 1970s, early 1980s) we were told less than 20% would require review.
- Early 1980s, APA Ethics Committee reported fewer than one-half of one-percent of complaints involved research.
- Why do we need more and more regulation?
- Or do we, really?

We were warned

Dwight D. Eisenhower, "Farewell Address,"
January 17, 1961:

*"The prospect of domination of the nation's
scholars by Federal employment, project
allocations, and the power of money is ever
present -- and is gravely to be regarded."*

Lost Talent

- 3 Honors students, to Law, etc.
- PhDs: "Never again"
- IRB admins tell children "no"

- Young academics have no perspective, vulnerable to the "It's always been that way" deflection.
- Senior faculty are going to have to do it.

Bureaucracy - 1

1. Start with a cage containing five apes. In the cage, hang a banana on a string and put stairs under it. Before long, an ape will go to the stairs and start to climb towards the banana.
2. As soon as he touches the stairs, spray all of the apes with cold water. After a while, another ape makes an attempt with the same result -- all the apes are sprayed with cold water. Turn off the cold water. If later, another ape tries to climb the stairs, the other apes will try to prevent it even though no water sprays them.

Bureaucracy - 2

3. Now, remove one ape from the cage and replace it with a new one. The New ape sees the banana and wants to climb the stairs. To his horror, all of the other apes attack him. After another attempt and attack, he knows that if he tries to climb the stairs, he will be assaulted. He quits trying.
4. Next, remove another of the original five apes and replace it with a new one. The newcomer goes to the stairs and is attacked. The previous Newcomer (step 3 above) takes part in the punishment with enthusiasm.

Bureaucracy - 3

5. Again, replace a third original ape with a new one. The new one makes it to the stairs and is attacked as well. Two of the four apes that beat him have no idea why they were not permitted to climb the stairs, or why they are participating in the beating of the newest ape.
6. After replacing the fourth and fifth original apes, all the apes which have been sprayed with cold water have been replaced. Nevertheless, no ape ever again approaches the stairs. WHY NOT?

And the answer is ...

"Because that's the way it's always been around here."

Innovate, innovate, innovate,
just don't change the way we do things,
after all, we have policies.

Policies truly trump.

I'll empty the bucket



Why bureaucrats were the first to go during the Revolution

American Sociological Assoc.

ASA Code of Professional Ethics:

- 1969: about 1,200 words.
- 1989: 4,675 words (over 3x)
- 1997: 15,247 (over 10x, including 3,663 words on enforcement).

(Adapted from R. Mitchell, 1999)

American Psychological Assoc.

APA Code of Ethics:

- 1992: 10,745 words
- 2003: 10,396 words

CPA Code of Ethics:

- 2000: 12,000+ words

(APA the exception to prove the rule?)