

IRB gripes? Show the data.

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In Relation to Behavioral and Social Sciences
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Disclaimer

This presentation is intended to promote the exchange of ideas among researchers and policy makers. The views expressed in it are those of the author as part of ongoing research and analysis and do not necessarily reflect the position of the US Department of Education or any other Common Rule department or agency.

My perspectives:

- **Regulator:** “That C.Rule guy”—working every day with regulators, researchers, IRBs, program staff and study subjects.
- **Interagency:** Chair, Social and Behavioral Research Working Group; member of HSRIG, CDAC, Committee on Science’s Social Behavioral and Economic Subcommittee; SACHRP Ex Officio; ED liaison with Federal Demonstration Partnership (FDP) and the President’s Commission for the Study of Bioethical Issues.
- **Planning and Evaluation Service,** US Department of Education.
- **Legislation:** Senior legislative staffer for member of Congress, Education and Labor Committee.
- **Researcher:** College faculty member and social and behavioral researcher.
- **Research consumer.** Nonprofit policy advocacy group use of research data.
- **Advocate of evidence-based practice:** JERHRE board, Campbell Collaboration participant, member of AERA, American Statistical Association and PRIM&R, etc.
- **Long time critic of IRBs and regulations** that needlessly hinder rigorous research.

Some concerns & the path ahead

1. IRB operations
2. Researcher's views
3. Why it matters
4. Empirically-informed regulation.

Common Complaints about IRBs

- **Takes too long**– the delays harm studies.
- **Costs too much.**
- **Flawed review:** IRBs Don't understand the research (e.g. qualitative research).
- **Undermines research** with requirements for informed consent, etc. “Don't talk to the humans”.
- **The “Nanny State”, “Ethical Imperialism”, and “Censorship”,** that make it impossible to do vital research.
- **Moral hazard,** making research impossible, biasing what research is conducted, driving research abroad.
- *“And besides, there is no significant risk in social and behavioral research.”*

Some problems with today's Common Rule system

- 1. Science has changed—the Common Rule hasn't.** Multisite, multidisciplinary studies, big data, etc. Modernize.
- 2. Operational issues:** reviews that too often:
 - Fail to reflect real risks.
 - Inconsistent (unequal protections, slowing research, ...)
 - Lack coordination among IRBs in multisite studies.
 - Lack transparency and accountability. When IRBs get it wrong there is often no appeal.
- 3. Is it working?** Largely an “evidence-free zone”.

from the dawn of modern scientific method:

***“Nothing is so firmly
believed as that which
is least known.”***

--Michel de Montaigne

(1533 – 1592)

Les Essais, (bk. 1, ch. 32)

- *“Perhaps the greatest irony of the entire IRB debate is how little of it is informed by actual, reliable research about the facts of the problem... examination reveals that virtually no scientific evidence is brought to bear on any aspect of the debate about how IRBs function.”*

--Illinois White Paper, 2005, p. 18

Critic 1:

“IRB review creates big burdens for researchers”?

Principal investigators on federal grants report that they spend about 42% of their time on “administrative burden”. IRB-related burdens rank highest.

of 24 measured burdens. (Federal Demonstration Partnership (FDP) “Burden Survey”)

Caveats: While the online survey had 6,295 respondents, note that:

- 1. Plenty of room for selection bias:** 26% response rate.
- 2. Precision of measurement:** IRB burden measures at 3.5 on a 5 point scale. (3 is “some burden”, 4 is “quite a bit”). In survey research it is common for respondents with no opinion or who are uncertain to select the middle point on a scale.
- 3. “IRB burden” has a measured burden similar to those for many other grant-related tasks** such as applying for grants, hiring and training staff, and providing performance reports to funders.

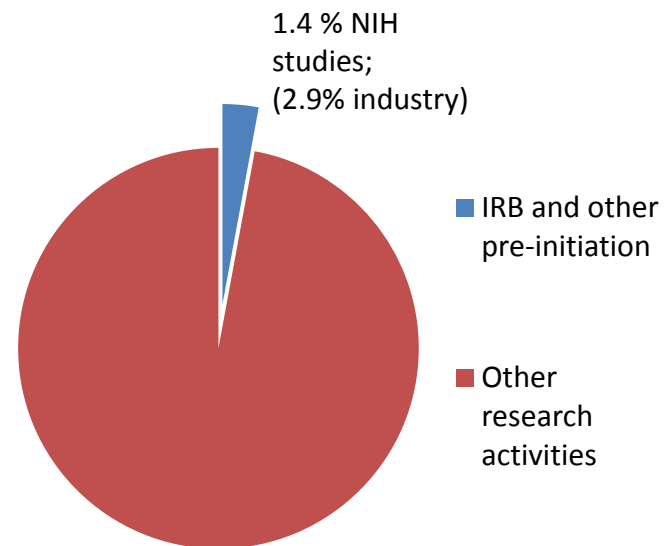
Critic 2 :

“ IRB review is too costly to researchers”?

Really?

- Data on the cost of IRB review as part of total research costs is scarce . (Most cost analyses focus on costs to institutions.)
- As first approximation consider:
Emanuel et al (2003). In a scenario for a high risk study of an experimental cancer treatment, all activities prior to initiation of human subjects research account for between 1.4% and 2.9% of total research time. (And 2.3%-4.7% of study costs.)
- Study recruitment is often far more costly, time consuming—and threatening to the ability to conduct research—than IRB review.

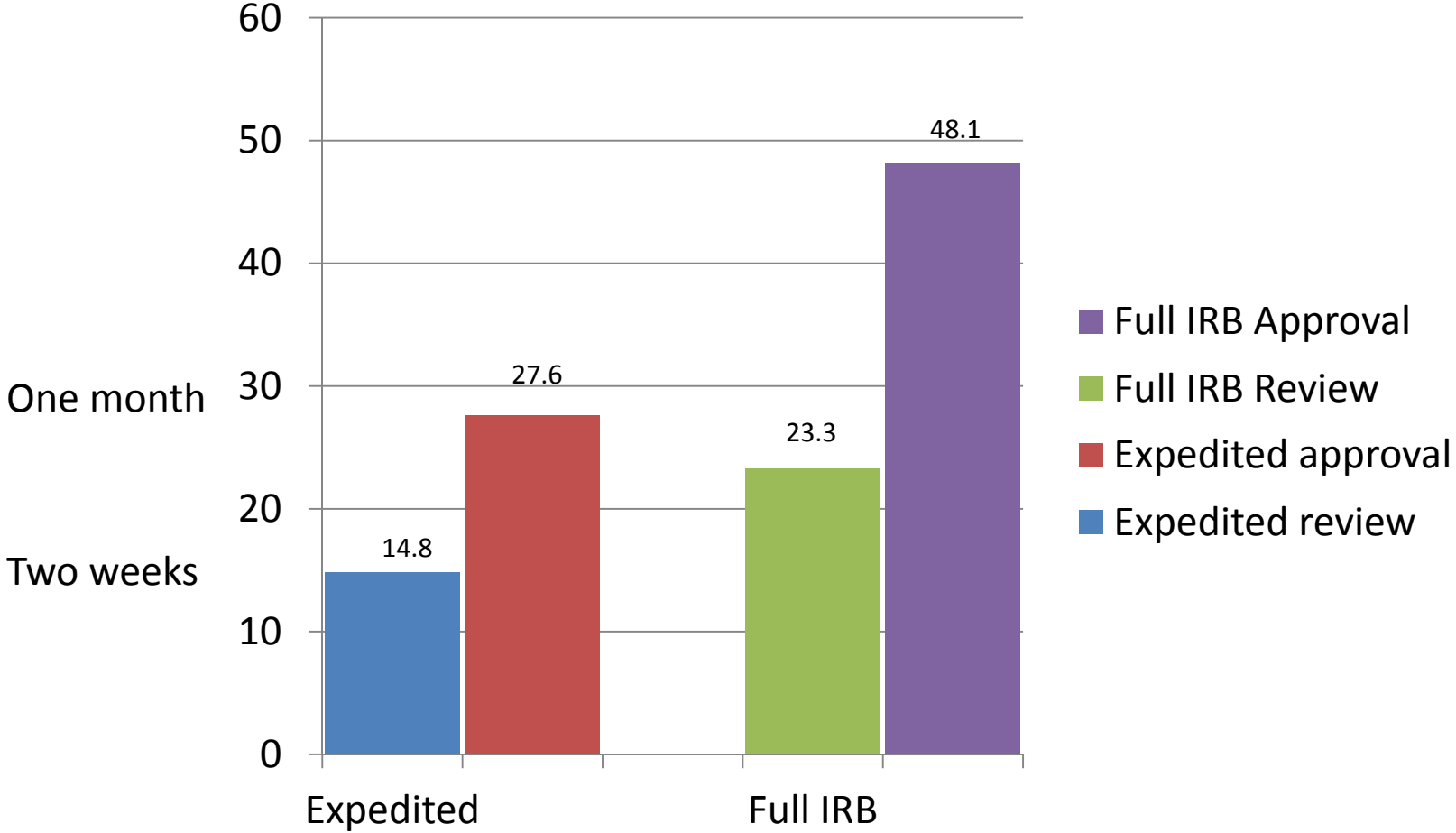
Time required for IRB review



Critic 3: "IRB review takes too long."

How long does it take?

Mean number of calendar days to complete IRB approval



Most IRBs meet monthly, some more frequently, others less frequently.
Source: Average of 2010 data for AAHRPP metrics and IRBNet Benchmark report

“Tail-risks”?

Some studies encounter extreme delays--- but why?

- Journal articles and blogs tell of studies that took much longer to clear—142 days, 252 days, 303 days, 966 days....
- **Data on review time—from both published articles and performance metrics --suggests that they are “black swans”,** rare but important events. Averages (48 days from submission to approval by full IRB) can obscure big problems in the functioning of the Common Rule system.
- **They are important, but not what usually happens**—raising the question “Why?”
 - **Little is currently known about these “black swans”.** Slow IRBs? Inept researchers? Risky studies? ...
 - In extreme event analysis, the forces at work often differ from the central tendency—in reworking regulations it is important to know what is happening here.

Not approved?

Few studies are not eventually approved by an IRB.

- AAHRPP Metrics report that 60% of those IRBs had not disapproved a single study in 2011 and about another 20% had disapproved a single study. Fewer than one-in-ten of those IRBs had disapproved more than two studies that year. The average AAHRPP-affiliated IRB had 297 active protocols in 2011.
 - Disapproved studies are routinely resubmitted.
 - Abbott and Grady's systematic review of empirical work on IRBs found a publication that reported that over a 12 year period one IRB rejected no study proposals.

Big time-savings from modest changes in IRB operations.

At Yale University research facilitation office the time from intake through development to IRB submission and approval averaged **80 days** in 2007. Now the same process takes **45 days**. The IRB and research office cut 35 days from that timeline through efficiencies in both the office and IRB processes.

University of Maryland School of Medicine: In March of 2010 it took **35 days** for full IRB approval for a clinical trial from the U of MD's School of Medicine which reviews more than 1,000 applications annually. After reorganizing IRB operations, in March 2010 that had dropped to **21 days (and was 13 days in February.)**

- **University of Nebraska:**

- **“Q: How long does it take to review an application for IRB approval?”**

- **A. It varies. The length of time depends both on the IRB and the investigator.** In 2007, the IRB reviewed 539 protocols. At certain times of the year, a large volume of protocols appear in the reviewing queue. More complex protocols often take more time. So far in 2008, the mean length of time from submission to approval for simpler protocols was 18-24 days, and for more complex protocols, 63 days. Sometimes, the investigator needs to make modifications to the research and to the protocol as a result of review. The faster you make these changes, the less time it will take for approval”.

Delay?

- A third of the time required for IRB approval is due to researchers' omissions and errors in providing information needed for review and responding to IRB comments at IRBNet institutions. When delays occur, they are often caused by investigators' failing to provide necessary information or tardiness in responding to IRB comments.
- A major determinant of how long IRB approval takes is how often IRBs meet. (The mode is monthly, sometimes less frequently during holiday season, summer, etc.)

In sum:

- **1. Researchers rate IRB review about as burdensome as other basic grant-related activities**, such as writing an annual performance report for the grant.
- **2. IRB review takes roughly 1.4% to 2.9% of total time devoted to the study.** This estimate lumps IRB review with all other activities prior to study initiation.
- **3. The vast majority of studies are approved—commonly on first submission.**
- **4. Most reviews are timely.** From protocol submission to approval, expedited review is completed on average in less than 28 days; full-IRB review in about 48 days. (Most IRBs meet monthly.)
- **5. Extreme delays are statistically uncommon**—and the causes are largely unstudied (e.g. risky studies, lagging researchers, “IRB ping-pong”, ...).

Critic 4: *“Social and behavioral researchers hate IRBs.”*

- Really?

Some surveys of researchers' attitudes and experiences with IRBs

- FDP “Faculty Workload Survey” (2012) web survey, 6295 participants, (26% response rate).
- Keith-Speigel et al (2006) “What scientists want...” 886 experienced biomed and SBR researchers, (39% response rate)
- Reeser et al (2008) medical center; 115 respondents, (33% response rate.
- Wisner et al (2011) Psychiatric researcher 125 respondents (35% response)
- Liddle & Brazelton (1996) psychology faculty at 10 public research institutions (25% response rate)
- DeVries & Anderson & Martinson (2006) 1,768 mid-career scientists who received NIH funding (response rates: 52% for midcareer; 43% for early career)
- Dyrbye et al (2008) medical education researchers 83 (76% response rate)
- Irvine (2011) online survey of 155 sexuality researchers (40% response rate)
- Pennell & Lepkowski (2009) 542 U Mich researchers (34% response rate)
- Ferraro et al (1993) views of the IRB at U ND 112 faculty
- “The Bell Study” (1998) over 2,000 respondents (including 491 IRBs).
- And ...

What do researchers really think?

- **The data does not support the conventional wisdom.**

Researchers report that while there is considerable room for improvement, they report strong support for protection of human subjects principles embodied in the Common Rule, report that the review process tends to protect study subjects and improve studies and report that IRB review is generally timely and appropriate.

 - In 89% of the 18 studies that ask researchers about their experiences and attitudes toward IRB review the majority of the researchers-- including in the largest and best designed studies--report positive experiences with their IRBs and positive attitudes toward the broader protection of human subjects system.
- **Biomedical and social and behavioral researchers largely agree on this.**
 - None of the studies report large differences between social and behavioral and biomedical researchers in their experiences and attitudes toward IRBs and the protection of human subjects in research. Social and behavioral researchers have often been highly visible critics of the Common Rule system, including arguments that the regulation imposes a biomedical model of science on social and behavioral studies where, arguably, that model does not fit. However, study after study reports little or no difference in how biomedical and social and behavioral researchers view the IRB system, including in levels of satisfaction.

Researchers' perspectives: Ideal IRBs --and Our IRB

<i>Importance of Elements in IRB performance (on a 7 point scale)</i>	<i>“Ideal IRB”</i>	<i>“Our IRB”</i>	<i>Gap: ideal vs our IRB on a 7 point scale</i>
<i>Timely review</i>	<i>6.52</i>	<i>6.43</i>	<i>0.10</i>
<i>Conscientious review of submitted protocols</i>	<i>6.53</i>	<i>5.86</i>	<i>0.67</i>
<i>Competency in distinguishing exempt from nonexempt research</i>	<i>6.29</i>	<i>5.48</i>	<i>0.81</i>
<i>IRB members don't allow personal biases to affect their evaluations of the protocol</i>	<i>6.44</i>	<i>6.17</i>	<i>0.27</i>
<i>No preconceived biases against particular research topics</i>	<i>6.14</i>	<i>5.45</i>	<i>0.69</i>
<i>No preconceived biases against particular research techniques</i>	<i>6.17</i>	<i>5.43</i>	<i>0.74</i>
<i>Open to innovative approaches to conducting research</i>	<i>6.18</i>	<i>5.28</i>	<i>0.90</i>
<i>Does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal policy whenever it perceives criticism outside the scientific community</i>	<i>6.33</i>	<i>6.08</i>	<i>0.25</i>

Medical and Social and Behavioral Researchers' Attitudes toward IRB review at the University of Michigan, 2009

	Med	SBR
IRB serves a useful purpose	88%	83%
IRB review adds protection	90	88
IRB is an ally in my research	71	64
The IRB required changes were reasonable	72	72
IRB interprets regulations too strictly	63	59
IRB required changes made it harder to achieve goals	33	36
IRB required changes improved protections of human subjects	44	44
The IRB understands its mission	88	84

Average Med/SBR gap of 3%

In sum:

- Researchers generally approve of the IRB system —albeit with desire for faster review, more responsive IRB staff, etc.
- Biomedical and social and behavioral researchers have very similar views of the IRB system—and both are interested in process improvements.
- There is no bright line between Med and SBR research, as noted by R. Levine for National Commission.

So...

“Why must we closely regulate activities that have minimal probability of causing minimal harm, especially when the current regulations add so little protection at significant cost and burden?”

--Scott Kim, (2009)

“IRB Oversight of Minimal Risk Research: Are we seeing the Big Picture?” presentation

Say what?

“Closely regulate”? Today most SBR does not require any IRB review under the Common Rule because:

1. It is “not human subjects research” as defined by the reg,
2. It is not funded by a covered source, and/or
3. It falls under one or more of the exemptions.
 - For example, surveys are exempt unless the private information collected is both sensitive (affecting employment, etc.) AND identifiable.
 - Many sensitive studies, such as the Belfast Project study of N. Ireland “Time of Troubles” are not reviewed by an IRB.

- **At the University of Michigan only about 4% of SBR studies go to full IRB.** For SBR studies that go to the UM IRB, 35% are deemed exempt and another 61% are expedited.

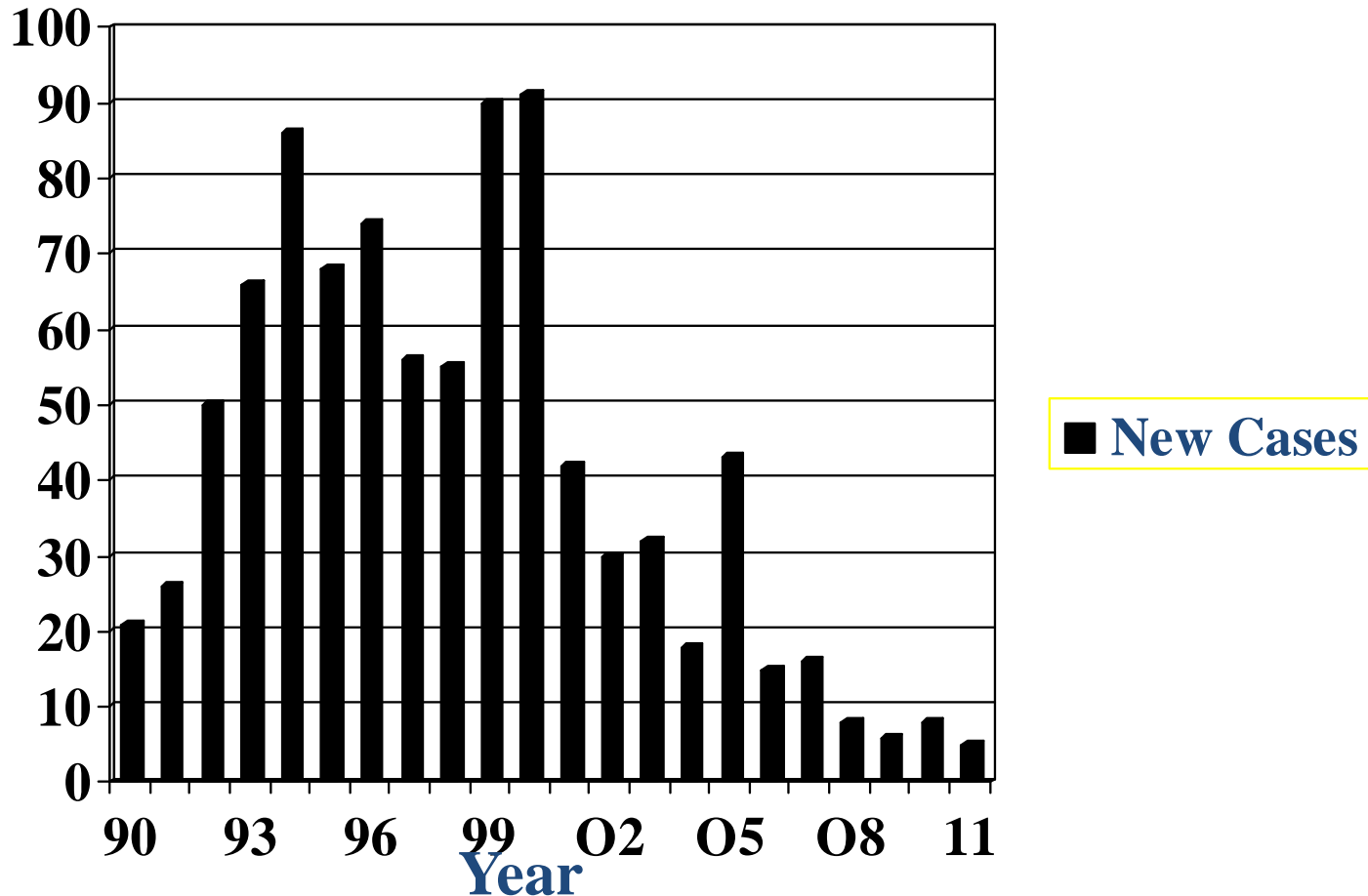
--Scott Kim, 2009

Coast-on-by at Colorado's Coast IRB?

Little data on whether IRB matters



OHRP Compliance Oversight New Cases Initiated – 1990-2011



“When the Feds come knocking”:

OHRP compliance reviews and enforcement 1990-2011

- New cases initiated from 2008-11 never exceeded 8 in any one year.
 - New cases peaked at 91 in 2001 (about the time OPRR was eliminated). Since 2001 the annual number of new cases never exceeded 42.
- The annual number of investigational visits never exceeded 6 from 1990-2001; the annual average was 3.3.
- Most cases are handled via phone calls, emails and letters. OHRP reviews most commonly focus on informed consent forms, IRB meeting minutes and other procedural issues. Little is known about the effectiveness IRBs in protecting research subjects.
- From 1990-2011, a total of 12 Assurances were suspended (i.e. an average of about one every other year) and 36 restricted (an average of 3 a year).

“The Iceberg”



No problems—or no reporting?

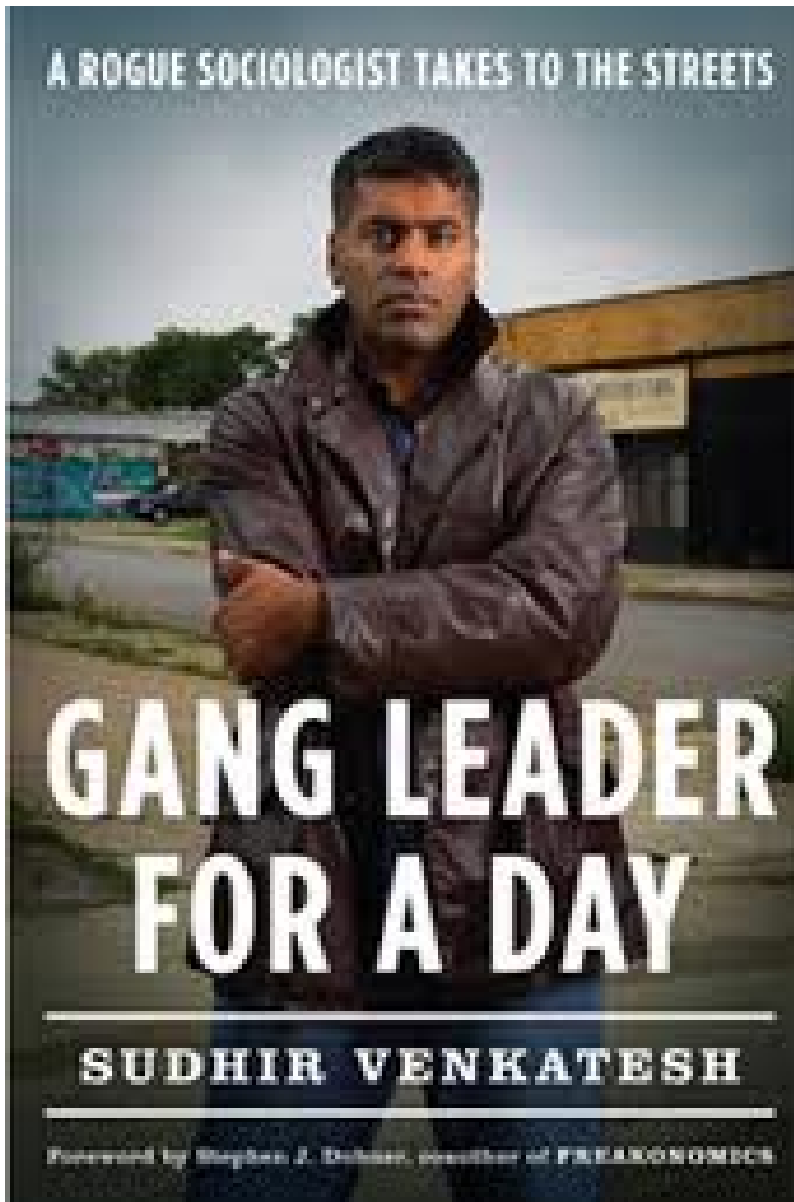
Is the answer “It’s not my job”?

- *“I can’t tell you whether our two undercover successful tests are isolated cases or the tip of the iceberg. What I can tell you is that given the history of human subjects testing, it’s hard to believe that anybody could be comfortable with the integrity of the current system.”* –Gregory Kurtz, GAO Managing Director Forensic Audits and Special Investigations, testimony to the House Subcommittee on Oversight and Investigations 2009.
- *“What in the devil is going on in your agency that allows you to think you can ignore the law and regulations governing the adequacy of IRBs and simply enter whatever is emailed your way and put the US government stamp of approval on an IRB? Nobody picked up on names like ‘Phake Medical Devices,’ ‘April Phuls,’ Timothy Wittless’ and Alan Ruse? Or the town of ‘Chetesville, Arizona?’”*
--Hon. Greg Walden, R-Oregon, ranking member, Subcommittee on Oversight and investigations..
- *“Many political scientists—especially those in the senior ranks— are either oblivious to the existence of IRBs or actively decide to sidestep them by not submitting their proposals for review”* --Dvora Yanow and Peregrine Schwartz-Shea, *PS: Political Science & Politics, PSONline* (July 2008)494. pp 483-494 .
- In ED nearly every report of noncompliance or unanticipated risk comes from parents or teachers familiar with the Common Rule due to medical contacts—or hearing about the “IRB” on TV’s medical dramas.

It's likely that SBR is like other fields— with most problems never reported.



- “Scam artist steal a documented \$3 billion a year from [older Americans], a mere fraction of the actual amount considering that only an estimated 4% of retirement age victims—just one in 25 according to various studies—ever report the crime” --AARP Bulletin.
- Most rapes are never reported. DOJ reports that 36% of rapes and 34% of attempted rapes were reported to police in 1992-2000.
- Only 1-out-of-7 errors, accidents and other events that harm hospitalized Medicare patients are reported. To be paid under Medicare, hospitals are supposed to track medical errors and adverse patient reactions, analyze their causes and improve care as a result. HHS estimated in 2012 that more than 130,000 Medicare patients experienced one or more adverse events in a single month.
- Airline controller errors rose dramatically, jumping 50% from 2009-2010 when changes in FAA reporting resulted in more voluntary reports from controllers. The Aviation Safety Action Programs encourages controllers to self-report errors in exchange for immunity from punishment.
- It has been argued that deaths reported to OHRP seriously underestimate the number of actual research-related deaths (e.g. Shamoo).
- And so on.



PhD student Sudhir Venkatesh had gained the confidence of many in the public housing complex, and had gotten individuals to share with him information on how much they were earning in the drug trade, prostitution, car theft, and various other “economic activities”. The gang leader and an associated housing project leader convinced him to provide information on what information he had gleaned from his interviews. He saw this as an opportunity to check on the credibility of the information that his study participant had provided.

Soon after his disclosure, he found he was being cold-shouldered and avoided by the residents. The book describes the interaction when he pressed one resident that he had gathered earnings information from for information on what had happened:

'Don't play with me. All that shit I told you. All them niggers I introduced you to. If you told me you were going to tell JT, they were making that money, I wouldn't have told you nothing.... 'JT is all over these niggers' C-Note said. He looked disgusted and spat on the ground. ...'He's taxing every one of them now' he added. 'And he beat the shit out of Parnell and his brother because he thought they were hiding what they were doing. They weren't, but you can't convince JT of nothing. When he gets his mind to something, that's it. And then he tells Jo-Jo and his guys that they can't come around no more because they were hiding things from him. Jo-Jo's daughter lives up in here. So now he can't see her.' C-Note kept talking, getting angrier and angrier as he listed all the people that JT was cracking down on. 'There's no way he could've found out if you didn't say nothing.'"

Venkatesh, *Gang Leader for a Day*, p. 203



“I’m just a Fulbright scholar...”

In 2008 ABC reported that ‘in apparent violation of US policy, Peace Corps and a Fulbright scholar were asked by a US embassy official in Bolivia to basically spy on Venezuelans and Cubans in the country. The Fulbright scholar John Alexander van Schaick said he was ‘told to provide the names, addresses and activities of any Venezuelan or Cuban doctors or field workers” he encountered while working in Bolivia” Peace Corps Volunteers reported that the same US embassy official had also asked them to gather such intelligence the previous summer.

(Project Camelot, Operation Condor redux, or ?)



It's only music.

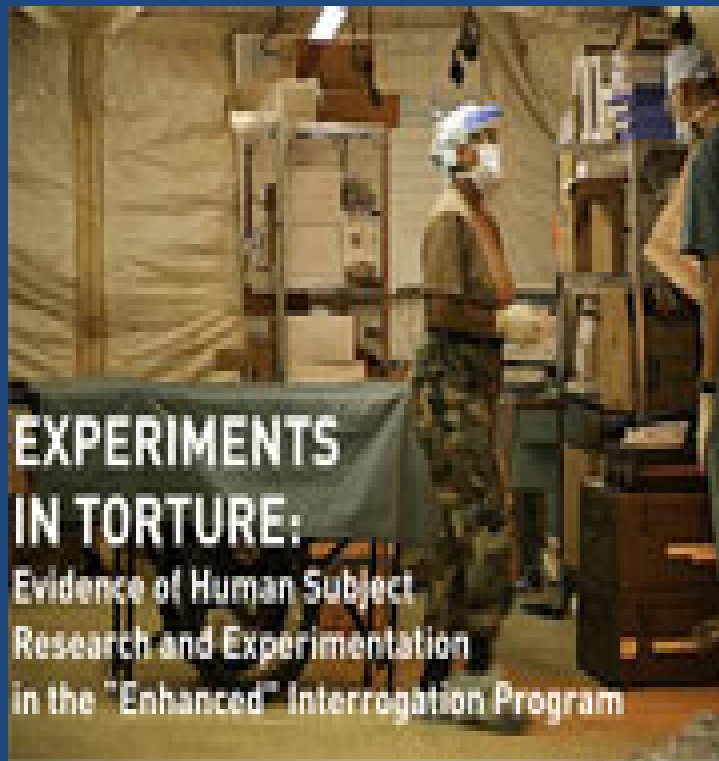
“Ngawan Chopel a Tibetan ethnomusicologist and former Fulbright scholar, was sentenced to 18 years in prison on trumped up spy charges. China accused Ngawang Choephel of being sent by the ‘Dalai clique with financial support of a certain foreign country,’ an obvious reference to the United States.” He was released years later by the Chinese, just prior to a visit to Beijing by the U.S. President.



Belfast Project (cf. “It’s only oral history”)



“Interrogation research”



JAMA

Commentary

Roles of CIA Physicians in Enhanced Interrogation and Torture of Detainees

Leonard S. Rubenstein, JD and BG (ret)
Stephen N. Xenakis, MD

JAMA 2010, 304(5) 569-570.



“The Trauma of Truth Telling: Effects of Witnessing in the Rwandan Gacaca Courts on Psychological Health”

[Karen Broome](#)

Department of Peace and Conflict Research, Uppsala University, Sweden and National Centre for Peace and Conflict Studies, University of Otago, Dunedin, New Zealand, karen.broome@otago.ac.nz; *Journal of Conflict Resolution*, 2010.

Abstract

Truth telling has come to play a pivotal role in postconflict reconciliation processes around the world. A common claim is that truth telling is healing and will lead to reconciliation. The present study applies recent psychological research to this issue by examining whether witnessing in the *gacaca*, the Rwandan village tribunals for truth and reconciliation after the 1994 genocide, was beneficial for psychological health.

“The results from the multistage, stratified cluster random survey of 1,200 Rwandans demonstrate that Gacaca witnesses suffer from higher levels of depression and PTSD than do nonwitnesses, also when controlling for important predictors of psychological ill health. Furthermore, longer exposure to truth telling has not lowered the levels of psychological ill health, nor has the prevalence of depression and PTSD decreased over time. This study strongly challenges the claim that truth telling is healing and presents a novel understanding of the complexity of truth-telling processes in postconflict peace building.”

Yanomami



“The recent appearance in the Brazilian press of two articles on the Yanomami Indians based on Napoleon Chagnon’s latest paper on Yanomami ‘violence’ [the article in Science]... has prompted us to call your attention to the extremely serious consequences that such publicity can have for the land rights and survival of the Yanomami in Brazil.” ... The Brazilian Anthropological Association (ABA) feels that it is fundamental **TO INSIST on the need to bring to the awareness of North American anthropologists the political consequences of the academic images they build about the people they study. The case of the Yanomami in Brazil, who have been suffering a brutal process of land expropriation which is justified in discriminatory images based on dubious scientific conclusions, are in this respect a particularly grave and revealing case...**We urge the AAA to take the necessary steps to call to the attention of the North American anthropological community the ethical and moral repercussions of their writings for critical situations such as this”

-- Robert Borofsky (ed) Yanomami: The Fierce Controversy and What we Can Learn from It, (2005)p.



Is it on the test?

Research meets praxis: NCLB etc.

- High-stakes test-based accountability--
Pass or fail—for students, teachers and schools.



Opportunity-to-learn risks in education research

“Bills Prod Schools to Hold Back Third Graders” Wall Street Journal, Feb. 13, 2012

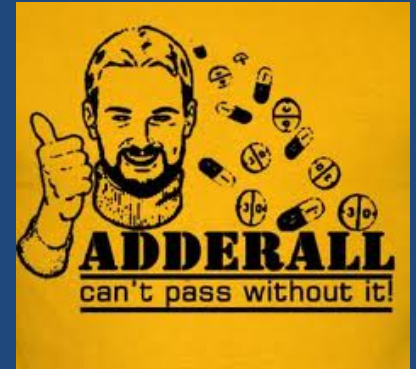
A child’s ability to read at the end of third grade is a strong predictor of subsequent performance in school.

Legislators in Colorado, New Mexico, Iowa proposed requiring students to repeat 3rd grade if they do not pass a reading test.

When tried in Chicago in the late 1990s a series of studies by the Consortium on Chicago School Research at University of Chicago found that, in general, retained students did no better in later years than students who had been promoted—but were more likely to drop out of school.

“Brain-enhancing Drugs Stir Safety, Ethics Debates”

Education Week, (Oct. 25, 2012)



“While less than 3% of secondary students reported ever using a prescription painkiller, tranquilizer or stimulant for fun, 62% reported they had used a prescription stimulant in order to be more focused at school, and 44% said they had used the drugs to be more focused for a job, sports or extracurricular activities.

Nearly 13% said they had friends who regularly used prescription stimulants to study and focus at school or work”

- --National Center on Addition and Substance Abuse, Columbia University, 2009: “Adolescent Substance Abuse: American’s #1 Public Health Problem”

“How to build a better learner”

--*Scientific American* (July 2011)



It's not just disclosure risks

Ethical researchers do not use interventions known to be iatrogenic

- ▣ “Scared Straight” “a 2002 meta-analysis of relevant research on nine such programs, found that ‘not only does it fail to deter crime, but it actually leads to more offending behavior.’”
- ▣ D.A.R.E. A meta-analysis of 20 rigorous studies found that the D.A.R.E. program had a less than small effect on reducing drug use (Cohen’s $d = 0.05$); the school-based drug intervention program also had a small effect on improving psychosocial behavior (Cohen’s $d = 0.10$). Some evidence suggests that D.A.R.E. may increase risk of substance abuse for some types of students.
- ▣ Many educational interventions have no measureable effect, or are worse than normal educational practice --and can pose serious risks to student “opportunity-to-learn” the tested curriculum.
- ▣ And ...

Characteristics and Context matter:



For example, research on the education of women is usually exempt as “normal educational practice”.

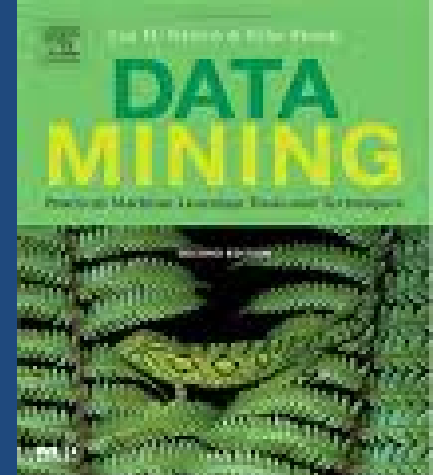
“Acid attacks, poison: What Afghan girls risk by going to school”

--By Allie Torgan, CNN

“Every day, you hear that somebody's thrown acid at a girl's face ... or they poison their water.” ... There were at least 185 documented attacks on schools and hospitals in Afghanistan last year, according to the United Nations. The majority were attributed to armed groups opposed to girls' education.



SBR often includes directly and/or indirectly identifiable data.



Big data challenge: checks-and-balances

Beyond the

“You have no privacy, get over it” world.

Cf Scott McNealy, SunMicrosystems



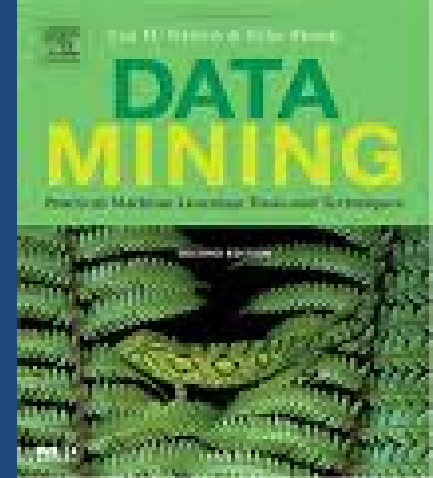
If you have three variables...

- Birthdate, sex, and ZIP code (5 digit)--alone uniquely identify 87% of the US population.

--Sweeney et al. "Confidentiality and Privacy of Electronic Medical Records"

- Education research often involves small samples, with longitudinal data, of students in classrooms in schools that may be linkable to external data sources to reidentify subjects.
- And ...

Proliferation of linkable data sets and evolution of data reidentification makes good data practices (and research ethics) increasingly important.



“Genetics Genealogy Databases Enable Naming of Anonymous DNA Donors”, Science (18 January 2013)

“By applying an algorithm to anonymized genomes from a research database and doing some online sleuthing with popular genealogy Web sites, researchers were able to guess the true identities of DNA donors”

- * **There are an increasing number of linkable data sets** to re-ID genetic and other data. For example, the FBI’s rapidly growing CODIS system has DNA SNPs for over 10 million people, and 450,000 unidentified people, readily searched if have access.

Who cares?

- When risks of disclosure are included in informed consent , e.g. for record linkage), people are less willing to participate. (Eleanor Singer et al.)
- A 2012 national survey by Forester Research found that **one-in-three consumers were concerned about companies having access to their behavioral data** from the internet. **More than 40% said they had stopped short of completing a transaction** on internet web site because of something they read in a privacy policy. (N.Y.T.)
- “A new US survey has just shown that **nearly half (45%) of US citizens feel that they have little or no control over the personal information** companies gather while they are browsing the Web or using online services such as photo sharing, travel or gaming. **Twenty-one percent of citizens have even stopped using these online services because of data protection concerns.** I believe that policy makers need to provide a solution. It is important both for consumers and for business...”
“Seventy-two percent of Europeans have told us in surveys that they are concerned about how companies use their personal data. They are especially worried about online privacy **and this is one of the most frequent reasons why people don’t buy goods and services online....”**
- --Viviane Reding, Vice President of the European Commission and Justice Commissioner of the European Union, “Q&A with Viviane Reding” , *New York Times*, (Feb 2, 2013).

Idiosyncratic outlier-- or symptomatic of a bigger problem?

- When “a study goes bad”, the challenge for the public, politicians, and regulators is to determine whether it is a “local” problem involving a particular study, researcher or institution—
Or whether it is evidence of a bigger problem that must be corrected with more enforcement, and/or new laws and regulations-- and/or avoiding research participation.



Reflections on reputation and its consequences:

From “excused research” to “no excuses research”?

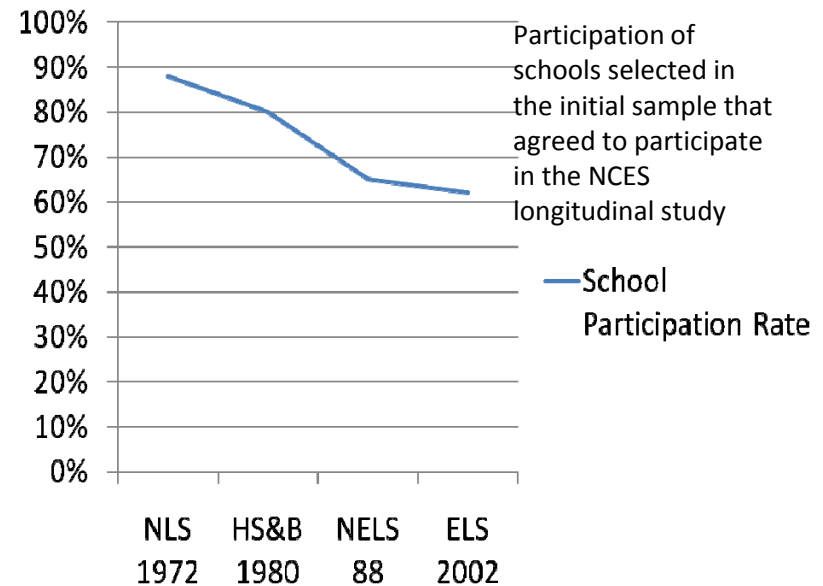
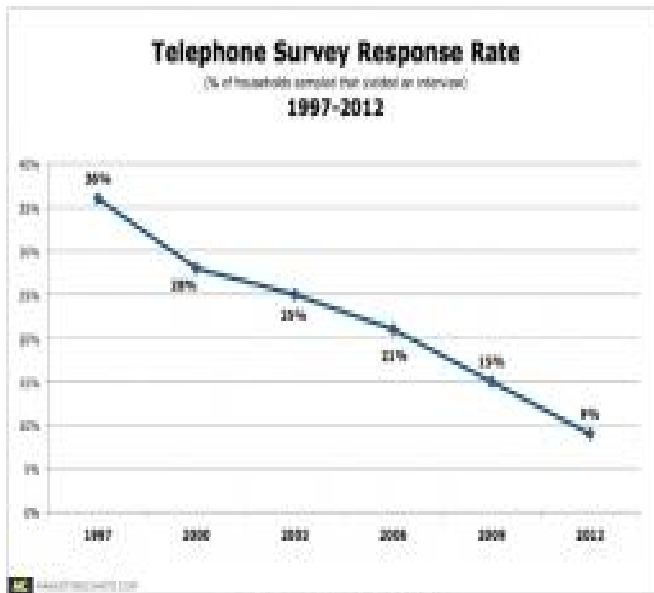
IRB review is a moderating variable in study recruitment and retention

Relatively few people participate in either SBR or Biomed research—and recruitment rates continue to fall, with outright rejections by contacted participants being a the largest component in the decline (e.g. Brick & Williams)

In SBR and other research recruitment, trust (generalized and specific) matters, sponsorship matters, dramatic recent events, etc. affect research participation (e.g. R. Groves).

You have a survey? Why bother?

Secular declines in participation/response rates
for survey research



Biomedical research recruitment

- ***“Participant recruitment is considered the most difficult aspect of the research process. Recent estimates indicate that 85% of trials do not conclude on schedule due to low participation accrual, 60% to 80% of clinical trials in the United States do not meet their temporal endpoint because of challenges in recruitment and 30% of trial sites fail to recruit even a single participant.... Despite its importance to successful research efforts, there is a dearth of literature reporting details of the recruitment process,”*** (Blanton et al).

Recruitment, IRBs and Trust

- **Design and field procedures matter.** Much of difference in participation of minorities is due to lack of access (Wendler et al). General distrust doesn't necessarily determine participation in specific studies (Dillman, E. Singer, etc.).
- **Procedures to boost recruitment face serious limits.** For example, while incentive payments boost recruitment, the effects are relatively small (E. Singer & Ye; Pew "high effort" surveys, etc.). In biomedical research, the Cochrane Collaboration reports a mean odds ratio effect size of 1.20 (median 1.09) (Treweek et al.)

Trust and participation

cf. “Leverage-Salience Theory of Survey Participation”

by R. Groves, E. Singer, A. Corning

- **Contagion: A few studies gone bad can fuel narratives that hinder or block future research.** (For example, a 1% increase in the mortgage delinquency rate increases the probability of a strategic default by up to 16.5%. Cf. vaccination fears; posing as public health campaign to kill Bin Laden that puts effort to eradicate polio at risk).
- Subjects are more willing to participate in studies conducted or sponsored by entities they know and trust (“sponsor effects”, “neighborhood effects”, etc.) Recruitment strategies emphasize building trust.
- Some people willing to participate in survey won’t if have to sign informed consent. Learning more of risks of record linkage decreases consent for record linkage (Eleanor Singer).



Flash mobs— the new world of human subjects protection?

TSA vs mom with a smartphone camera

Disabled child crying in her wheelchair vs Airport security

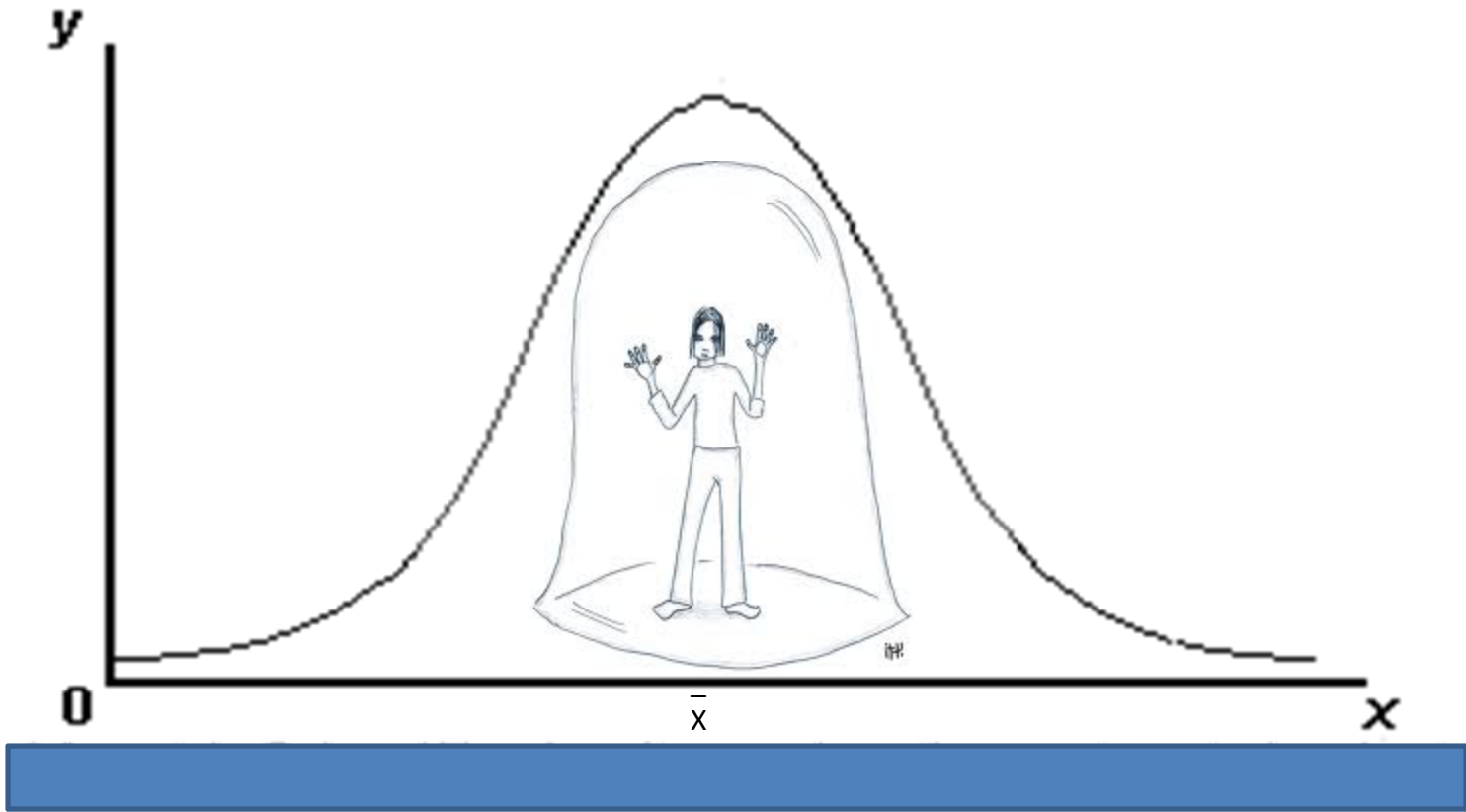
A three year old girl in a wheelchair and her upset parents as security agents take away the crying child's beloved stuffed doll. The mother records it all on her smart phone. When posted on the internet, the five-and-a-half minute video goes viral, triggering wide media coverage. The Transportation Security Administration apologizes to the family for the “unfortunate incident”, and changed staff training and other procedures. (NYT, March 5, 2013)

Confronted by a woman with a Facebook account, big bank backs down.

“In the internet age, the impact of consumer distrust is amplified: anyone can organize and participate in a protest. Participants do not need to gather physically; 60% of US adults use social media such as Facebook—and 66% of those users use it to encourage other people to take action....When a major bank attempted to charge a \$5 monthly fee for its debit card, a California woman created a Facebook event, dubbed “Bank Transfer Day” and invited her followers to transfer their accounts from large banks to credit unions that day. In the five weeks leading up to that day there was massive media coverage—and billions of dollars in deposits were reportedly transferred. Faced with the Facebook protest, the bank reversed its policy.

—Sarah Bloom Raskin, Board of Governors, Federal Reserve System, Feb 28, 2013.

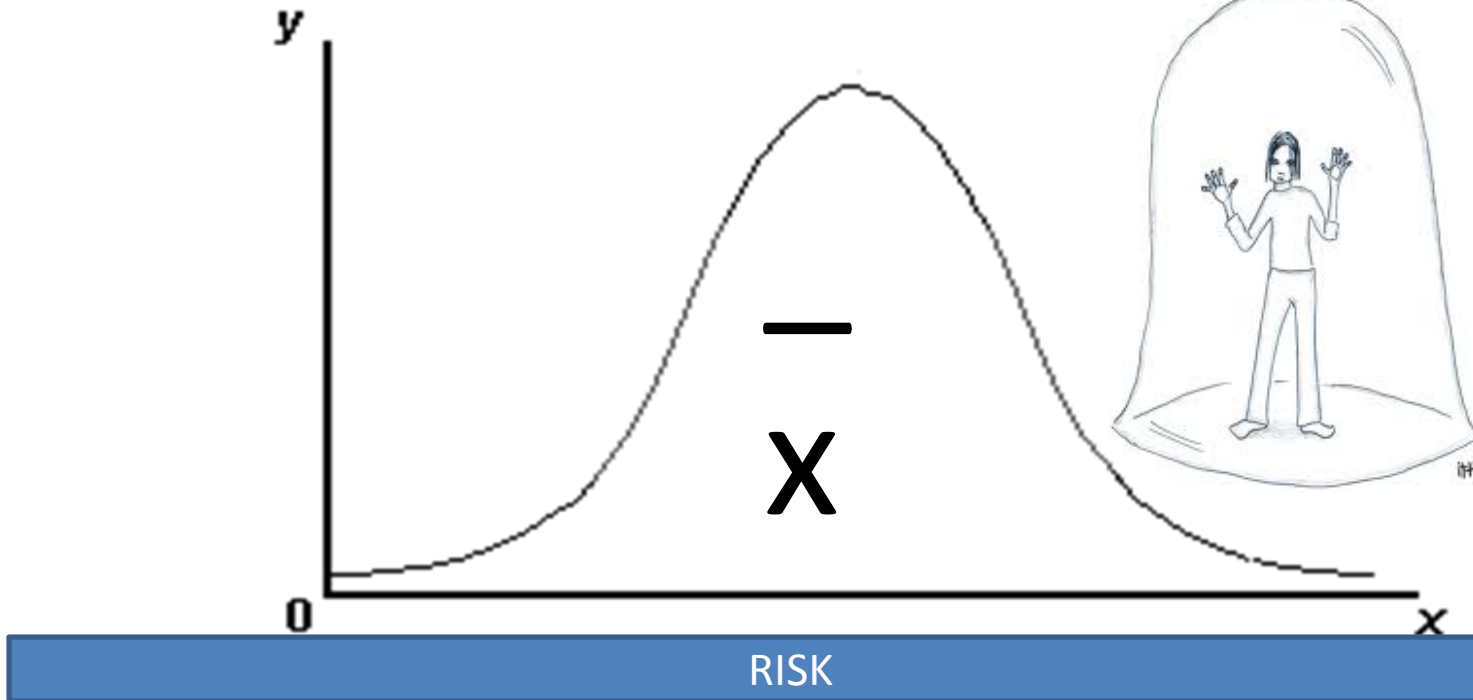
Regulators and IRBs typically focus on this:



The bell curve and the bell jar—

The public and media often focus on this:

Public perception:
“flash mob, media, etc.”



Long tails in SBR research—
meet blogs, media and flash mobs

FROM “BIG DATA” TO “NO DATA”?

Sometimes it just takes one study-gone-bad to change laws and regs

Even a few studies gone bad can trigger serious barriers to future research:

1. **American jury study** (Wichita jury component) → Congress banned recording jury proceedings (1953).
2. **USPHS “Tuskegee” and Common Rule** (long shadows of Guatemala, MKUltra, etc.)
3. **J. Hopkins education surveys** → Cited in creation of Family Education Privacy Act (FERPA) regulating student records and PPRA regulating surveys of students.
4. **CHEERS** (EPA observational study of pesticide exposure in children → new EPA protection regulation (2006)
5. **“Regulatory reign of terror”** after Jesse Gelsinger, Ellen Roche deaths etc. (VCU survey) (Abolition of Office for Protection from Research Risks (OPRR) and creation of OHRP.) (2000)
6. GAO sting of Coast IRB etc. led to FDA requiring its IRBs to register (2009)
7. Vaccinations: public trust (autism, Bin Laden, etc.)
8. Studying civil strife and genocide after Belfast Project?
9. Risks in low income housing after Kennedy Krieger?
10. And...



A new privacy statute enacted,
on average, each 3 ½ years.

The Presidential Commission for the Study of Bioethical Issues identified 11 separate privacy statutes enacted by Congress from 1970-2009.

In sum

- The Common Rule created a system of decentralized regulation—so that politicians and bureaucrats inside the Beltway do not determine what scientific research is conducted.
- Arguably, the Common Rule is a notable success story—including in SBR. Since it was adopted nearly a quarter of a century ago:
 - The quantity and quality of research have continued to grow.
 - Few reports of serious problems/unethical research in the US
 - Unlike many other statutes and regulations, it has been robust—largely stable since 1991.
 - And the policy model has been adopted around much of the planet.

Review bias:

“The Galileo Problem”

“Agenda-setting, self-censorship, ...:
IRBs’ secret function?”

Cf. “Normal science” vs. “paradigm challenging”
science (Kuhn)

Little systematic data, but enough information to require a closer
look, e.g.:

- Jack Katz (*The Seductions of Crime*, etc.)
- Ceci et al: IRBs and sensitive topics
- Irvine: Sociologists studying sexual behaviors
- Hyder et al: foreign researchers’ view of politicization in US IRB review
- M. Levine: “IRB Review as a cooling out mechanism”...
- And

Empirically-Informed Regulation:

“Toward a culture of persistent regulatory experimentation and evaluation”

“Our regulatory system...must measure and seek to improve the actual results of regulatory requirements..... [E]ach agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. –Executive Order 13563 (2011)

cited by Cass R. Sunstein, in “*Empirically Informed Regulation*”.

“The first step toward a culture of regulatory experimentation and evaluation is to write the statutes governing regulatory programs so that the regulations are implemented in ways that they lend themselves to experimental or quasi-experimental evaluation....

“Clearly it is not sufficient to merely devise regulations in such a way that they are intrinsically testable; we have to fund the evaluations of new regulations. An easy way to achieve this would be for the president to sign an executive order mandating that all new regulations must include provisions for collecting data that allow for evaluations of their effectiveness.The funds...should be used for evaluations by independent research groups. “ ...

--Greenstone, (pp. 118-119)

Achieving
Effective Human Subjects Protections
And
Rigorous Social and Behavioral Research
Recommendations to

The Human Subjects Research Subcommittee,
Committee on Science,
National Science and Technology Council

By

The Social and Behavioral Research Working Group

February 8, 2005



IN SUM:
**CAREFUL WHAT
YOU WISH FOR.**



No one pretends that IRBs are perfect or all-wise. Indeed, it has been said that IRBs are the worst form of governing research except for all those other forms that have been tried from time to time.

--apologies to Goethe and Churchill.



Thanks!

We look forward to working with you for effective protection of human subjects, rigorous research, and better policy and practice.

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Additional References

This presentation is based in large part on three papers that are in preparation by the author:

- *“IRBs: Tales and Long Tails”* (on IRB operations)
- *“What Do Researchers Think About IRBs? Surveys of Researchers’ Attitudes Toward IRB Review”*
- *“Risks real but rare: Low probability, high magnitude risks in ethics review of proposed research”*