

IRBs and the regulation of trust

Raymond De Vries
 Bioethics Program, Department of Medical Education, and
 Department of Obstetrics and Gynecology
 University of Michigan Medical School
 Ann Arbor, MI 48109
 USA



rdevries@umich.edu

IRBMed 2008 Education Symposium
 May, 2008

TRUST



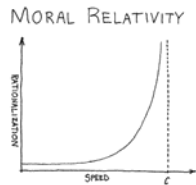
Main Entry: trust
 Pronunciation: \ˈtrʌst\
 Function: *noun*

Eymology: Middle English, probably of Scandinavian origin; akin to Old Norse *trast* trust; akin to Old English *træowe* faithful — more at true

Date: 13th century

1 a: assured reliance on the character, ability, strength, or truth of someone or something
b: one in which confidence is placed

Bioethics and Research Ethics: Born of mistrust



The end of trust in research

Tusgeek



Nuremberg



A reasonable response to research scandals:

A system for the protection of human subjects

Code of Federal Regulations
TITLE 45 — PUBLIC WELFARE
 Department of Health and Human Services
PART 46
PROTECTION OF HUMAN SUBJECTS

SUBPART A—
 Basic HHS Policy for Protection of Human Research Subjects

SUBPART B—
 Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

SUBPART C—
 Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

SUBPART D—
 Additional Protections for Children Involved as Subjects in Research



U.S. Department of Health & Human Services
 OFFICE OF HUMAN SUBJECTS PROTECTION
 OFFICE FOR HUMAN SUBJECTS PROTECTION

But:

What happens when we attempt to organize/regulate trust?



Bureaucratizing trust

Bureaucracy ≠ bad

Bureaucracies are characterized by:

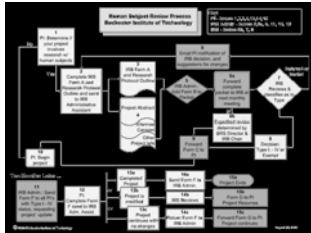
- 1) Specialization/division of labor
- 2) Hierarchy
- 3) Written regulations
- 4) Universalism
- 5) Record keeping
- 6) Administrative staff, and
- 7) Defined career structure

But...
Predictable things happen in bureaucracies....

Noble intent/bureaucratic result

- Complexity
- Goal displacement
 - From 'protection of subjects' to 'protection of institutions'
- Corruption of the process
 - The rise of for-profit IRBs
- Confusing situations
 - The unanticipated

Complexity



Research Ethics Committees
(REBs, IRBs, METCs)

Goal displacement

Rejuvenating a Foundering Institutional Review Board: One Institution's Story
Kenneth De Vito, JD, PhD, Gregory Haster, JD, PhD, and Michael J. Lewis, MD, PhD

Academic Medicine, Vol. 82, No. 1 / January 2007

Despite the generally high quality and work ethic of the individuals who served on the IRB committee, reviews, deliberations, and decisions still suffered under the old system from a recurring inability to identify and unravel the most relevant and pressing issues in a research proposal. Some reviewers, for example, might have identified noncritical punctuation errors or anomalies in internal processing documents that would never be seen or read by a human subject, or required consistent use of capitalization throughout an informed consent document. In addition, the committee would sometimes change language that had been approved on a virtually identical protocol in previous

Corruption of the process

Slate Tuesday, Dec. 13, 2005

Ethics for Sale: For-profit ethical review, coming to a clinical trial near you.

Carl Elliott and Trudo Lemmens

Slate

Ethics for Sale: For-profit ethical review, coming to a clinical trial near you.

...the ethics review of more than half of all new drug submissions to the Food and Drug Administration is handled by a single for-profit IRB, Western Institutional Review Board in Olympia, Wash.

...At the Fabre Research Clinic in Houston where research subject Garry Polsgrove died, the ethics review was conducted by a for-profit IRB run by Louis Fabre, the clinic owner.

For profit regulation (con't)

Problems:

1. Western IRB (WIRB) oversaw tests in California and Georgia in the 1990s for which doctors were criminally charged and jailed for lying to the FDA
2. WIRB settled a lawsuit after it approved a placebo-controlled trial for a Genentech psoriasis drug in which a patient was severely injured. . .
3. When reviewing protocols for Johns Hopkins University, WIRB reversed a previous decision under pressure from a clinical sponsor, using a panel dominated by alternate members.

The *PLoS Medicine*

July 2006 | Volume 3 | Issue 7 | e309

¿ Confusing situations ?

Case 203

IRB reviews a protocol for a drug study in local obstetrics department:

- Drug is already approved
- OB department is facing budget shortfall
- Drug rep is “helping out”
- Study is scientifically sound [open label]

What happens when we bureaucratize trust?

The peculiar problems of bureaucratizing trust

1. Who do you trust (to regulate trust)?
2. Response of the “untrusted”
 - a. *Oh yeah?* The problem of justice
 - b. *Who, me?* The problem of overregulation
3. Trust and the organization of science

1. Who do you trust? (Who gets to decide?)

- Who are the members of the research ethics committee?
 - 45 C.F.R. §46.107: IRB Membership (the **United States**)
 - *Wet Medisch-Wetenschappelijk Onderzoek Met Mensen* [Medical Research Involving Human Subjects Act], Section 16. (the **Netherlands**)

45 C.F.R. §46.107

Each IRB shall have **at least five members** . . . The IRB shall be sufficiently qualified through the experience and expertise of its members, and the **diversity** of the members, including consideration of **race, gender, and cultural backgrounds** and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects . . .

45 C.F.R. §46.107

No IRB may consist entirely of members of one profession... Each IRB shall include **at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas**... Each IRB shall include **at least one member who is not otherwise affiliated with the institution** and who is not part of the immediate family of a person who is affiliated with the institution.

What is the defining feature of IRB membership?

IDENTITY

Wet Medisch-Wetenschappelijk Onderzoek Met Mensen

The members of the committee must include at least **one doctor**, persons with **expertise in the law, research methodology, and ethics**, and a person charged with the task of examining protocols specifically from the **subject's point of view**.

Notice the difference:
Who do you trust?

Identity (USA)

vs.

Expertise (NL)

Do we have a mismatch in the USA?

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Identity becomes expertise

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This difference shapes the work of ethics review:

1. The kind of questions asked
2. The revisions requested
3. The procedures to be followed

2. Response of the “untrusted”

Oh yeah?
The problem of justice

Who, me?
The problem of over-regulation

Oh yeah?

PROTECTING HUMAN SUBJECTS
U.S. DEPARTMENT OF ENERGY, OFFICE OF BIOLOGICAL AND ENVIRONMENTAL RESEARCH
Fall 2006

Surprises? How researchers view IRBs

Report suggests that the way review boards see themselves and the way researchers see them may be very, very different

The good news? *The good news from the survey is that 38% of the researchers expressed satisfaction with their IRBs.*

www.ethicsresearch.com

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Researchers want respect/trust

An IRB that works with investigators to find mutually satisfying solutions whenever disagreements exist.

An IRB that gives a complete rationale for any required changes to or disapprovals of protocols.

An IRB that responds in a timely manner to investigators' inquiries about its processes and decisions.

ETHICS & BEHAVIOR, 15(4), 339-349
Copyright © 2005, Lawrence Erlbaum Associates, Inc.

The IRB Paradox: Could the Protectors Also Encourage Deceit?

Patricia Keith-Spiegel and Gerald P. Koocher

The efforts of some institutional review boards (IRBs) to exercise what is viewed as appropriate oversight may contribute to deceit on the part of investigators who feel unjustly treated ...

Paradoxically, **excessive protective zeal by IRBs may actually encourage misconduct by some investigators.**

The IRB Paradox: Could the Protectors Also Encourage Deceit?

Many angry investigators who confided their experiences to us expressed the belief that **their deceitful actions were fully justified and necessary in the interest of continuing their contributions to science unfettered**

2. Response of the "untrusted"

Oh yeah?

The problem of justice

Who, me?

The problem of over-regulation

Who, me?

I'm not the one you should be regulating!

Mission Creep in the IRB World
SCIENCE VOL 312 9 JUNE 2006

All this has generated a trend in which **researchers increasingly think of IRBs as the "ethics police."** In fact, all researchers must take primary responsibility for professional, ethical conduct. Our systems should reinforce that, not work against or substitute for it

I'm not the one you should be regulating!

Mission Creep in the IRB World
SCIENCE VOL 312 9 JUNE 2006

The Dysregulation of Human Subjects Research
JAMA, November 14, 2007—Vol 298, No. 18

Informed consent, anticipatory regulation and ethnographic practice

Elizabeth Murphy*, Robert Dingwall

SOCIAL SCIENCE & MEDICINE

Robert Dingwall, Confronting the Anti-Democrats: The Unethical Nature of Ethical Regulation in Social Science. 2006 Address to the BSA Medical Sociology Group.


Anticipatory regulatory regimes are inimical to ethnographic research . . . We do not suggest that we should . . . leave matters to the individual consciences of researchers. Rather, **we need to develop and strengthen professional models of regulation which emphasise education, training and mutual accountability.**

Robert Dingwall, Confronting the Anti-Democrats: The Unethical Nature of Ethical Regulation in Social Science. 2006 Address to the BSA Medical Sociology Group.

PoLAR: The Political and Legal Anthropology Review
(Vol. 30, No. 2)
Charles L. Bosk

1. *The mission creep or bureaucracy run amok complaint*
2. *The inappropriate model argument*
3. *The fetish of written consent objection*
4. *Journalists are allowed to do what we seek to do without fetters*
5. *The 'chilling effect' fear*
6. *There is no evidence that IRBs have been very successful in preventing just those abuses that they were designed to create argument*

Sociology vs. the OHRP
American Sociological A'ssn meetings



December, 2007

Presidential Address 757

Legality, Social Research, and the Challenge of Institutional Review Boards

Malcolm M. Feeley

Comment on the Presidential Address 787

"Turn off the oxygen . . ."

Robert Dingwall

The Perverse Consequences of IRBs

Do Investigators Have Rights?

The International Significance of IRBs

What Are the Costs of Regulation?

Institutional Review Blog
<http://institutionalreviewblog.blogspot.com>

News and commentary about Institutional Review Boards
Oversight of the humanities and social sciences

<http://institutionalreviewblog.blogspot.com>

1. Who do you trust

2. Response of the untrusted

3. Trust and the organization of science

Do researchers actually do what they say they will do?

NORMAL MISBEHAVIOR: SCIENTISTS TALK ABOUT THE ETHICS OF RESEARCH

RAYMOND DE VRIES
University of Michigan

MELISSA S. ANDERSON
University of Minnesota

BRIAN C. MARTINSON
HealthPartners Research Foundation

JERURE
Journal of Empirical Research on Human Research Ethics

**Science today:
Highly competitive**

People are doing things like that more, to chop their competitors, to get a leg up on them. And it's, in a way, almost being forced to do it. Because it's just, it's too competitive.

Science today: Runs like a business

So the whole thing -- science is business, and so it is just all money. At one level, nobody cares what you are doing.... The whole intellectual content of -- the whole idea of science as intellectual inquiry -- becomes very secondary.

Science today: Beset by (ridiculous) rules


If you ask why are the rules being bent, it's, in some cases, because **too many rules** have been implemented that obstruct you getting the necessary things done . . . there get to be so many rules and you're doing anything you can to dodge around those rules without totally stepping over the line . . . **they implement more rules and then there's more individuals that go, like, 'This is a ridiculous rule, how do I get around that?'**

Vol 435 | June 2008

COMMENTARY

Scientists behaving badly

To protect the integrity of science, we must look beyond fabrication, fabrication and plagiarism, to a wider range of questionable research practices, argue Brian C. Martinson, Melissa S. Anderson and Raymond de Vries.

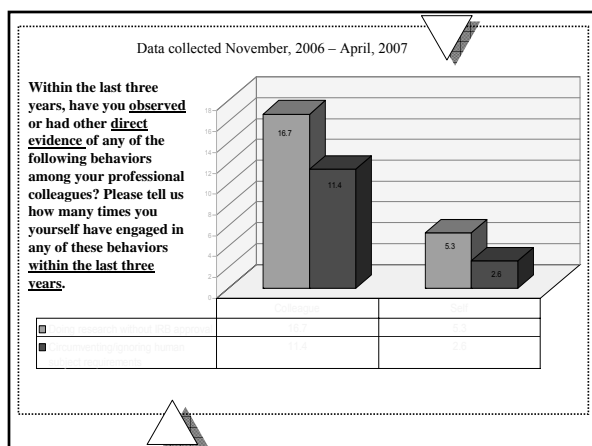
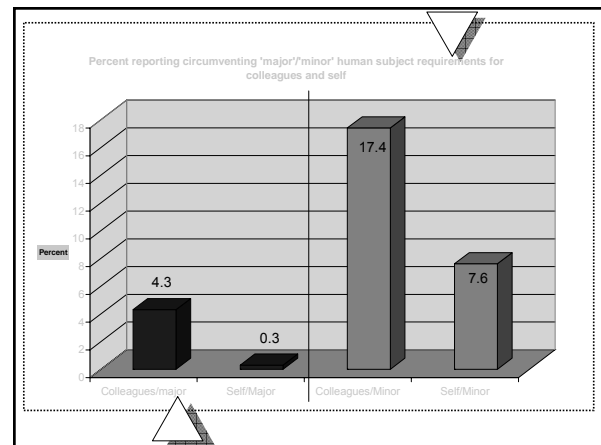


The ten behaviours	All	Mid-career	Early-career
1. Falsifying or tampering research notes	0.8	0.9	0.6
2. Reporting false aspects of human subject requirements	0.3	0.3	0.4
3. Reporting false being informed to those whose participation is based on their consent	0.2	0.4	0.3
4. Reporting on unpublished research subjects or clients that may be identifiable on publication	1.4	1.3	1.4
5. Using another's ideas without obtaining permission or giving due credit	1.4	1.7	1.0
6. Unethical use of confidential information in connection with one's research	1.7	2.4	0.9
7. Copying text from other people's work without permission requests	4.6	4.0	5.3
8. Copywriting other's work against human subject requirements	3.4	4.0	4.0
9. Copywriting other's work of their ideas or intellectual contributions	10.3	10.1	9.8
10. Changing the design, methodology or results of a study in response to research findings	16.3	20.6	9.9

Other behaviours

11. Publishing the same data or results from one's own publications	4.7	5.9	3.4
12. Reporting research progress at a conference	10.0	10.3	7.4
13. Introducing data of methodology or results in posters or proposals	10.8	10.4	8.9
14. Using unpublished or unpublished research findings	10.1	10.6	9.2
15. Using unpublished or otherwise unpublished data from analysis based on age	10.1	10.3	10.5
16. Using unpublished or otherwise unpublished research data	10.1	10.3	10.5
17. Using unpublished or otherwise unpublished research data	10.1	10.3	10.5

Mean age (years) of those who observed behaviours: all = 36.0, mid-career = 41.0, early-career = 31.0



Bad apples or the structure of science?

Let's look at mentoring:

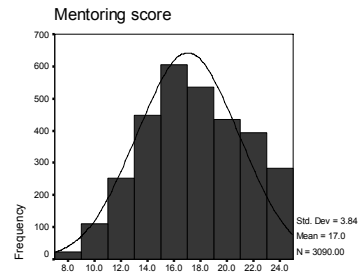
- What do young scientists learn from their mentors?



"As my mentor, I sometimes question the advice you've given..."

1. In your graduate program, postdoctoral work or related professional experience, how much of the following kinds of help have you received from your mentor(s)? (Circle one response per line.)

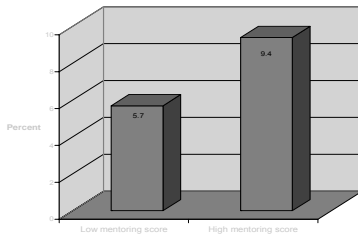
	None	Some	A lot
a. help in developing professional relationships with others in your field	1	2	3
b. assistance in writing for presentation and publication	1	2	3
c. instruction in the details of good research practice	1	2	3
d. assistance in obtaining financial support	1	2	3
e. instruction in writing grant and contract proposals	1	2	3
f. continuing interest in your progress	1	2	3
g. emotional support when needed	1	2	3
h. help in learning the art of survival in your field	1	2	3



Lo = 1 - 16; Hi = 17 - 34

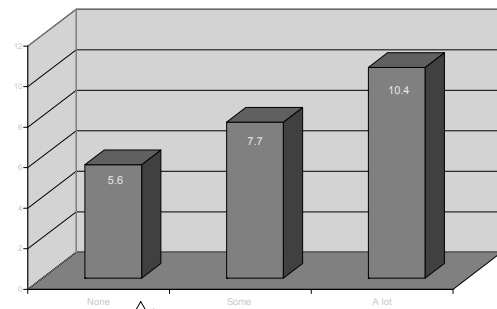
Mentoring and circumvention of 'minor' aspects of human subject regulation

Self report of circumvention of minor aspects of human subject requirements by mentoring score



$\chi^2 = 14.3$
df = 1, p < .001

Self report of circumvention of minor aspects of human subject requirements by 'mentoring in survival' score



$\chi^2 = 11.7$, df = 2, p = .003

Beyond regulation: How do we promote 'good' science?

- If 'bad' science is the question, regulation may not be the answer,
OR
- There is more than one way to skin a cat



"You have to learn how to stay," Jim Rice said. "What do I have to do? If I've got to cheat, I got to cheat. I don't care. I want to be in the big leagues."

New York Times
April 8, 2007
"The Road to Success Is Paved by Cheating"

A new approach to regulation?



Bad apples



Organization of science

Rethinking the environment of science

Thinking about the bureaucratization of trust

1. Who do you trust (to regulate trust)?

Thinking about the bureaucratization of trust

Identity or expertise?

2. Response of the “untrusted”
 - a. *Oh yeah?* The problem of justice
 - b. *Who, me?* The problem of over-regulation

Thinking about the bureaucratization of trust

Identity or expertise?

The need for respect and appropriate regulation

3. Trust and the organization of science

Thinking about the bureaucratization of trust

Identity or expertise?

The need for respect and appropriate regulation

Improving the working conditions of scientists

Acknowledgements

This research relies in part on my collaboration with **Brian S. Martinson** and **Melissa A. Anderson** on projects supported by the Research on Research Integrity Program, an ORI/NIH collaboration, with financial support from the National Institute of Nursing Research (Brian Martinson, PI). This research was also funded by an NIH Mentored Research Scientist Award (Raymond De Vries, PI)



Raymond De Vries

Bioethics Program

University of Michigan Medical School
Ann Arbor, MI 48109

rdevries@umich.edu

