Introduction to Research Ethics

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Ethics in Research and Publications

Contents

1. Scope; Ethics and Etiquette
2. Scandals and Ironies of our time
3. Research Ethics – What, Why, How
4. Ethics Review vs Scientific Review
5. Research protocol vs Research Proposal
6. What constitutes ethical research ?

Scope
Ethics and Etiquette

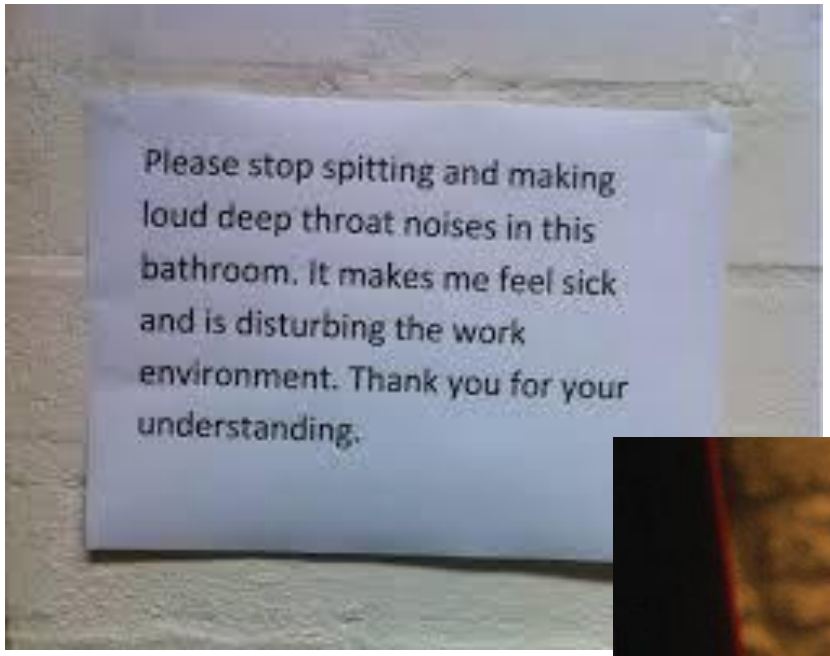
Ethics

MORAL aspects of human behaviour, individually and socially. Mostly translated into : “restriction” and “instruction” → morally deliberated.

Etiquette

Accepted code of behaviour among people in a group or society. Also translated into : “restriction” and “instruction” → not specifically morally deliberated.

Etiquette


Please stop spitting and making loud deep throat noises in this bathroom. It makes me feel sick and is disturbing the work environment. Thank you for your understanding.

Moral Deliberation

Compare

Dress code during a reception in presidential palace (courtesy)
Dress code for a doctor when examining patients (courtesy)
Obey traffic signs (order and safety)
Hypertensive patients should not eat internal organs (health)
Students must not exchange sms during class (order)

With

One must not steal (moral → humanity, religion)
One must not rape (moral → humanity, religion)
Informed consent in research (moral → respect for person)
Assessment of risk and benefit in research (moral → beneficence)
Research subjects allocation and selection (moral → justice)

Age of Accelerated Advancement

Human History Timeline:
500 Years

1500
- Renaissance
- Movable type
- Europe/Americas linked

Pop.: 500 million

1600
- Scientific Revolution
- Microscope, telescope, **bacteria discovered**
- Suspension bridge
- World map
- 2 yr. circumnavigation

Pop.: 600 million

1700
- Adding machine
- Nation state

Pop.: 700 million

1800
- Steam engine
- Electric motor
- Photography

Pop.: 900 million

1850
- Industrial Revolution
- Canning, Refrigerator
- Telegraph, Telephone
- 2 mo. circumnavigation
  - **bacteria-disease link**

Pop.: 1 billion

1900
- Autos, Blimps
- Submarines
- Phonograph, wireless
- Vacuum tube
- Electric typewriter
- 2 week circumnav.

Pop.: 1.7 billion

1950
- Birth control
- Jet, Satellite
- H-Bomb
- Solar cells
- Xerox, car phones
- 2 day circumnav.

Pop,: 2.5 billion

2000
- Computers
- Internet
- Space travel
- DNA
- Laser

Pop.: 6 billion

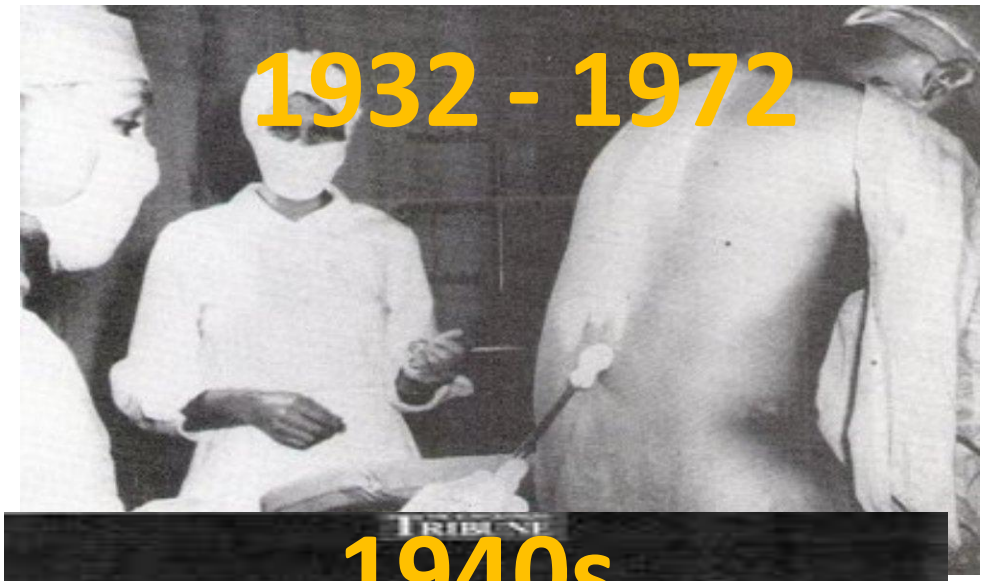
Wealth Source

LAND_____**MINES/MINERALS**_____**KNOWLEDGE**_

Political Unit

CITY STATE__**NATION STATE**_____**REGIONAL GROUPINGS**___

20th Century Irony of Human Research Ethics



The Tuskegee Syphilis Study
(Black Men in US; 1932 - 1972)

1932 Study starts. Black men with syphilis are enrolled, are told to be treated, but are not treated in actuality. Not treating is hypothesized as giving some medical benefits.

1945 Penicillin accepted as treatment of choice for syphilis.
1947 USPHS establishes "Rapid Treatment Centers" to treat syphilis; men in study are not treated, but syphilis declines.

1969 CDC reaffirms need for study and gains local medical societies' support (AMA and NMA chapters officially support continuation of study).

1972 Study ends.
1973 Congress holds hearings and a class-action lawsuit is filed on behalf of the study participants.

Macon County Health Department

ALABAMA STATE BOARD OF HEALTH AND U. S. PUBLIC HEALTH SERVICE COOPERATING WITH TUSKEGEE INSTITUTE

Dear Sir:

Some time ago you were given a thorough examination and since that time we hope you have gotten a great deal of treatment for bad blood. You will now be given your last chance to get a second examination. This examination is a very special one and after it is finished you will be given special treatment if it is believed you are in a condition to stand it.

If you want this special examination and treatment you must meet the nurse at _____ on _____ at _____ M. She will bring you to the Tuskegee Institute Hospital for this free treatment. We will be very busy when these examinations and treatments are being given, and will have lots of people to wait on. You will remember that you had to wait for some time when you had your last good examination, and we wish to let you know that because we expect to be so busy it may be necessary for you to remain in the hospital over one night. If this is necessary you will be furnised your meals and a bed, as well the examination and treatment without cost.

REMEMBER THIS IS YOUR LAST CHANCE FOR SPECIAL FREE TREATMENT. BE SURE TO MEET THE NURSE.

Macon County Health Department

Dilemma of Pharma companies

- **Conflicting commercial interest**
- Not publishing unfavorable results on trials to clinicians and general public

June 2006 · Vol. 55, No. 6

InfoPOEMs®

PATIENT ORIENTED EVIDENCE THAT MATTERS

Antidepressant drugs increase suicide risk in children

Hammad TA, Laughren T, Racoosin J. Suicidality in pediatric patients treated with antidepressant drugs. Arch Gen Psychiatry 2006; 63:332-339.

- **Clinical Question:** Are antidepressant medications associated with an increased risk of suicidal behavior in children?

Nature. 2004 Sep 16;431(7006):232.

Congress may force drug firms to reveal clinical trial data.

Check E.

PMID: 15371992 [PubMed - indexed for MEDLINE]

The Reboxetine Scandal — How Should We Make Medical Trial Data Available?

POSTED BY KENT ANDERSON · NOV 16, 2010 · 10 COMMENTS

FILED UNDER BMJ, CLINICAL TRIAL, PFIZER, PUBLICATION BIAS, REBOXETINE, RESEARCH

Recently, a meta-analysis published in the *BMJ* showed once again that upstream filtering by commercial entities can have severely deleterious effects on patients. In conducting a meta-analysis, a group of researchers found that 74% of the data from clinical trials had been suppressed leading up to the approval of reboxetine for the acute treatment of severe depression. When these missing patient data were added back in, the beneficial effects reported for reboxetine vanished while a host of risks emerged. Essentially, industry pulled a fast one.

Research Ethics

What

Research ethics is specifically interested in the analysis of ethical issues that are raised when people are involved as participants in research.

Why

Does ethics review make the research ethical ?

To protect human participants
To ensure servitude to public interests
To ensure ethical soundness (risk-benefit management, informed consent, confidentiality, etc)

How – What kind of studies

Involving humans
Biomedical research
Social science research
Others ?
High risk vs Low risk

Nancy Walton; researchethics.ca

Research Ethics; Why is it important ?

1. To promote the **aim of research**; knowledge, truth, avoidance of error

2. To promote the values that are essential to **collaborative work**; accountability, mutual respect, and fairness

3. To ensure that researchers can be held **accountable to the public**

4. To build **public support** for research

5. To promote **social responsibility, human rights, compliance with the law, and health & safety**

Resnik, 2012

Why Bother ?

The Statistics

US Data : 0.01% – 1% of researchers/year

(Shamoo and Resnik, 2009)

BUT…..

The "Bad Apple" VS The "Stressful/Imperfect Environment" Theories; Combination Theory

Many of the deviations that occur in research may occur because researchers simply do not know or have never thought seriously about some of the ethical norms of research.

The Ethical Struggle in Research

"The primary ethical struggle in clinical research, therefore, is that a few individuals are asked to accept burden or risk as research subjects in order to benefit others and society……

Christine Grady in "Principles & Practice of Clinical Research"

What constitutes ethical research ? Belmont Report 1978

Principles of		Guidelines for
Respect for person (Autonomy)	→	Informed Consent
Beneficence/ Non-Maleficence	→	Risk vs Benefit Assessment
Justice	→	Selection of Subjects

What constitutes ethical research ? Six Criteria for Human Involvement

1. Sound moral reasoning for involving human as subjects

2. …the anticipated results will justify the performance of the experiments… (bad science = bad ethics)

3. …unprocurable by other methods or means…

4. …risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved…

5. Free and Informed Participation

6. Justice; Fair distribution of benefits and burdens

Ethical Decision Making in Research

What is the problem or issue ?

What is the relevant information ?

What are the different options ?

How do ethical codes or policies as well as legal rules apply to these different options?

Are there any people who can offer ethical advice?

The main point is that human reasoning plays a pivotal role in ethical decision-making but there are limits to its ability to solve all ethical dilemmas in a finite amount of time.

Ethical Decision Making in Research

Which choice could stand up to further publicity and scrutiny?

Which choice could you not live with?

Think of the wisest person you know. What would he or she do in this situation?

Which choice would be the most just, fair, or responsible?

Which choice will probably have the best overall consequences?

Resnik, 2012

Research protocol vs Research Proposal

RESEARCH PROTOCOL:

- EXPLAIN a research plan → PLAIN, AS IT IS
- The term "research protocol" is commonly used in ethics review
- Normally composed of contents in research proposal PLUS researcher's explanation on ethical considerations such as: privacy/confidentiality, risks, vulnerability, terms of collaboration, declaration of conflict of interests, community sensitivities and benefit, honorarium/incentives to participants

RESEARCH PROPOSAL:

- PROPOSE a study → ARGUE, PROMOTE
- The term "research proposal" is commonly used in funding evaluation or study-related research work
- Normally composed of Background, Literature Review, Objectives, Methodologies, Expected Outcomes

Ethics Review vs Scientific Review

ETHICS REVIEW:

- Ensure compliance to ethical standards
- Ethics review requires methodological soundness, first of all
- Normally required before commencing ANY study on human

SCIENTIFIC REVIEW:

- Ensure adherence to methodological standards
- Usually for funding evaluation → return of investment consideration
- May also be for study-related research work

Training in Ethics is a must prior to entering research field

CITI PROGRAM | Collaborative Institutional Training Initiative at the University of Miami

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- Animal Care and Use (ACU)

Responsible Conduct of Research (RCR)

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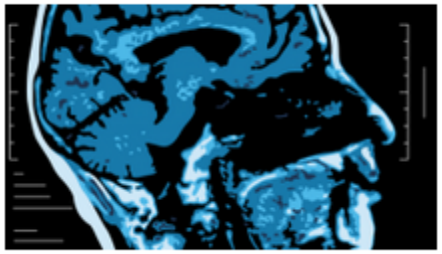

University of Pennsylvania

Neuroethics

Ended a month ago

course info |class archive

View class archive

"Science, as long as it limits itself to the descriptive study of the laws of nature, has no moral or ethical quality and this applies to physical as well as the biological sciences"

(Sir Ernst Boris Chain in Social Responsibility and the Scientist, New Scientist 1970)

Thank you

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