Geospatial Data: The Role of the IRB

2013 CGA Conference on Geospatial Privacy, Law, and Policy

May 03, 2013

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Acknowledgements

- Dr. Patricia Pearl O'Rourke –

  Director, Human Research Affairs at **PARTNERS HealthCare**
  - Massachusetts General Hospital
  - Brigham and Women's Hospital
  - Spaulding Rehabilitation Network
  - Newton-Wellesley Hospital
  - North Shore Medical Center
  - McLean Hospital
  - Nantucket Cottage Hospital
  - …

- Conflicts of Interest
  - None

Institutional Review Board (IRB)

- Most academic research centers
- Focus on biomedical research
- Oversight of human subjects in research

- Defined by federal law as:
  - systematic collection and dissemination of data from or about living human subjects
  - very broad definition!!

IRB Members

- scientists and laypeople, including:
  - MD/PhDs
  - RNs
  - Chaplaincy
  - patient representatives/community members
  - consultants

IRB and GIS

- Knowledge of GIS within IRB
  - Varies by institution
  - Varies by IRB members
  - No consensus (at this time)
  - Overall, little understanding of what GIS is and data implications
  - Juxtaposition of "traditional research methods" vs cutting edge technology

Lessons learned through History and Biomedical Research:

- Why is it important to have oversight? Why do we need to have IRBs?
- →overriding principle: protection of human research subjects

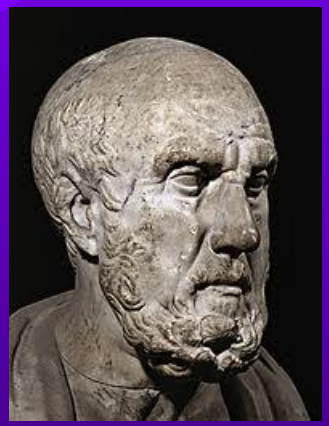
- GIS yields data, which can include subject data.

  If that data is not protected → the subject can be harmed (even if willful harm is not intended).

Very early on…

- 6th Century BC

  Meat and vegetable experiments on young Jewish prisoners in Book of Daniel



- 5th Century BC: Hippocrates

  Primum non nocere ("first do no harm")

- 1st Century BC

  Cleopatra devises experiment to test theory that takes 40 days to become a male fetus and 80 days to a become female fetus. Has female prisoners who are sentenced to death impregnated and subject to operations to open the womb at specific times of gestation.

1700s

- 1796: Edward Jenner

  Infects 8 year-old James Phipps with pus taken from a cowpox pustule, becomes immunized against smallpox.

  Repeats the experiment on other children, including his 11-month old son.

  Coins term *vaccine* from the Latin ‘vacca’ for cow.

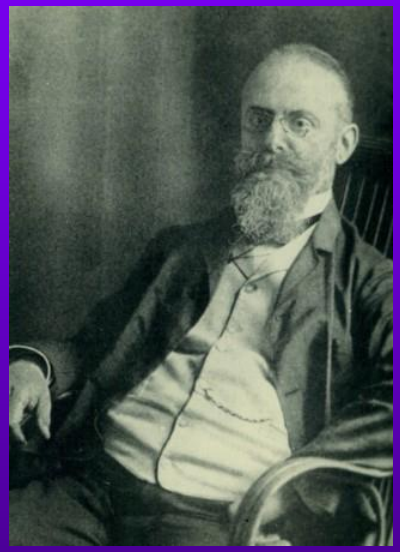
1800s

- 1865: Claude Bernard

  Introduction to the Study of Human Experimentation: "Never perform an experiment which might be harmful to the patient even though highly advantageous to science or the health of others."

1800s

- 1882: Albert Neisser injects women with serum from patients with syphilis, infecting half of them.

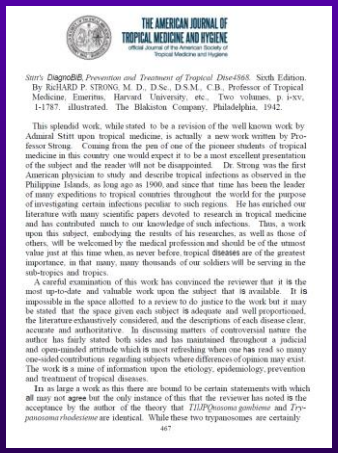


- Neisser know today as discoverer of the bacteria Neisseria Gonococcus, which causes gonorrhoeae in humans.

1900s

- 1900: Walter Reed injects 22 Spanish immigrant workers with Yellow Fever. Each subjects signs informed consent and receives $100 if they survive and $200 if the get the disease.

- 1906: Dr. Richard P. Song, a U.S. Army medical officer, conducts experiments with cholera on prisoners in the Philippines, killing 13. Later becomes Professor of tropical medicine at Harvard (1913).



THE AMERICAN JOURNAL OF TROPICAL MEDICINE AND HYGIENE

official Journal of the American Society of Tropical Medicine and Hygiene

Stitt's Diagnosis, Prevention and Treatment of Tropical Diseases. Sixth Edition. By RICHARD P. STRONG, M. D., D.Sc., D.S.M., C.B., Professor of Tropical Medicine, Emeritus, Harvard University, etc., Two volumes, p. i-xxv, 1-1787. illustrated. The Blakiston Company, Philadelphia, 1942.

This splendid work, while stated to be a revision of the well known work by Admiral Stitt upon tropical medicine, is actually a new work written by Professor Strong. Coming from the pen of one of the pioneer students of tropical medicine in this country one would expect it to be a most excellent presentation of the subject and the reader will not be disappointed. Dr. Strong was the first American physician to study and describe tropical infections as observed in the Philippine Islands, as long ago as 1900, and since that time has been the leader of many expeditions to tropical countries throughout the world for the purpose of investigating certain infectious pecilliar to such regions. He has enriched our literature with many scientific papers devoted to research in tropical medicine and has contributed much to our knowledge of such infections. Thus, a work upon this subject, embodying the results of his researches, as well as those of others, will be welcomed by the medical profession and should be of the utmost value just at this time when, as never before, tropical diseases are of the greatest importance, in that many, many thousands of our soldiers will be serving in the sub-tropics and tropics.

A careful examination of this work has convinced the reviewer that it is the most up-to-date and valuable work upon the subject that is available. It is impossible in the space allotted to a review to do justice to the work but it may be stated that the space given each subject is adequate and well proportioned, the literature exhaustively considered, and the descriptions of each disease clear, accurate and authoritative. In discussing matters of controversial nature the author has fairly stated both sides and has maintained throughout a judicial and open-minded attitude which is most refreshing when one has read so many one-sided contributions regarding subjects where differences of opinion may exist. The work is a mine of information upon the etiology, epidemiology, prevention and treatment of tropical diseases.

In as large a work as this there are bound to be certain statements with which all may not agree but the only instance of this that the reviewer has noted is the acceptance by the author of the theory that *T.I.P.Pyosoma gambiense* and *Trypanosoma rhodesiense* are identical. While these two trypanosomes are certainly

467

1900s

- 1938: Dr. Wendell Johnson (University of Iowa) does a study where he induces orphans to stutter. Becomes one of the world's leading speech pathologists, has a building at UI named after him.

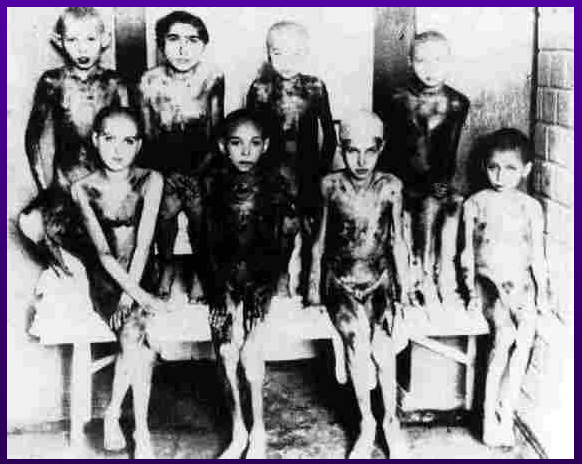
Sino-Japanese War/WWII

- 1938: Japan establishes Unit 731, under direction of Dr. Shiro Ishii.

  Conduct experiments on Chinese prisoners and Chinese population, including:
  - poison gas experiments
  - aerial spread of chemicals and biological agents
  - vivisections ("field tests") on infected soldiers

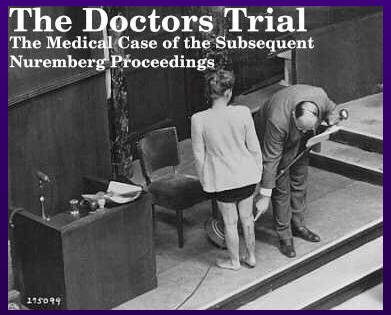
WWII

- 1939-1945: Nazi Germany Experimentations
  -register all twins for genetic research
  -sterilization experiments
  -high altitude and low pressure experiments
  -infectious disease experiments (Typhus, Malaria)
  -freezing experiments
  -phosphorus burn experiments
  -coagulation experiments
  -seawater experiments



Nuremberg Doctors Trial

- December 6, 1946: US military tribune, opens criminal proceedings against 23 German physicians and administrators.
- Willing participation in war crimes and crimes against humanity.
- Used thousands of concentration camp prisoners without their consent
- Most died or permanently crippled
- Testimony of 85 witnesses; 1,500 documents



Nuremberg Code: 1947

1. Voluntary consent of the human subject is absolutely essential
2. Experiment should yield fruitful results for the good of society, unprocurable by other ways
3. Experiment should be based on prior knowledge and anticipated results should justify the study
4. Experiment should avoid all unnecessary physical and mental harm
5. Anticipated death or disabling injury are only allowable if the researchers serve as subjects
6. Benefit must be greater than risk
7. Proper preparations to protect subjects against injury, disability, or death
8. Experiment conducted only by scientifically qualified persons
9. Subject at liberty to withdraw at any time
10. Researcher must be prepared to terminate the experiment at any stage, if believes that continuation is likely to cause harm

Tuskegee Syphilis Study

- 1932-1972, Alabama
- Conducted by US Public Health Service
- 600 black men enrolled
  - 399 with syphilis
  - 201 without syphilis
- Told would receive treatment for "bad blood"
- Examinations, blood, chest X-Rays, spinal taps
- Never told purpose of study, but told would receive free medical examination, medication (not for syphilis), and burial insurance
- Never given treatment for syphilis
  - Until 1945: mercury and bismuth - toxic, not very effective
  - 1945: penicillin
- Up to 100 died of syphilis, possibility of passing infection onto partners and their children in utero

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1933 with about 600 black men.

Belmont Report

- 1979: Basic Ethical Principals
  - **Respect for Person**
    - person is autonomous agent (informed consent)
    - persons with diminished autonomy must be protected (children, illness, mental disability, prisoners, students)
  - **Beneficence**
    - do no harm
    - maximize benefits, minimize harms
  - **Justice**
    - fairness (selection of research subjects)
    - according to needs

HIPAA:
Health Insurance Portability and Accountability Act

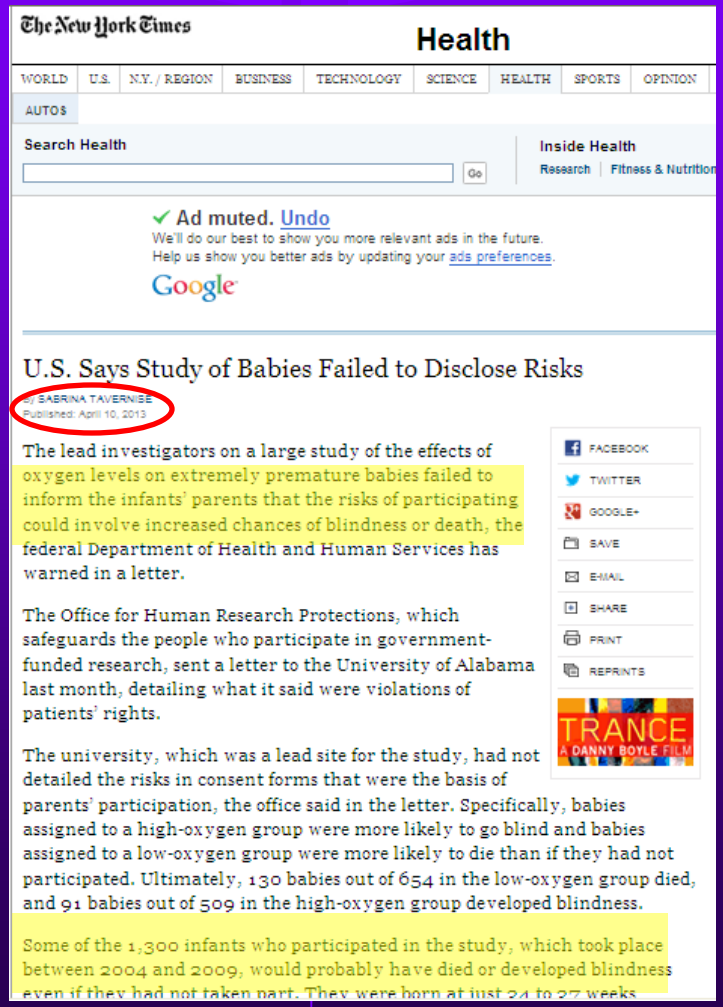
- 1996: Protection of individually identifiable health information.

- How might this relate to GIS, even if you are not doing biomedical research?

And still today…

"…failed to inform the infants' parents that the risks of participating could involve increased chances of blindness or death… "

1,300 infants participated in the study



The New York Times

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U.S. Says Study of Babies Failed to Disclose Risks

By SABRINA TAVERNISE

Published: April 10, 2013

The lead investigators on a large study of the effects of oxygen levels on extremely premature babies failed to inform the infants' parents that the risks of participating could involve increased chances of blindness or death, the federal Department of Health and Human Services has warned in a letter.

The Office for Human Research Protections, which safeguards the people who participate in government-funded research, sent a letter to the University of Alabama last month, detailing what it said were violations of patients' rights.

The university, which was a lead site for the study, had not detailed the risks in consent forms that were the basis of parents' participation, the office said in the letter. Specifically, babies assigned to a high-oxygen group were more likely to go blind and babies assigned to a low-oxygen group were more likely to die than if they had not participated. Ultimately, 130 babies out of 654 in the low-oxygen group died, and 91 babies out of 509 in the high-oxygen group developed blindness.

Some of the 1,300 infants who participated in the study, which took place between 2004 and 2009, would probably have died or developed blindness even if they had not taken part. They were born at just 24 to 27 weeks

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Oversight:
What determines oversight of biomedical human research?

- Federal Law
- Case Law
- Condition of Grant Award
- Media (New York Times, Boston Globe, etc)
- Ethics of Researcher (GIS, GPS, and other novel technologies and methods)

Example of using personal data without permission…

- The Immortal Life of Henrietta Lacks
- origin of the HeLa cell line
- Extra biopsies taken for research purposes – without knowledge or consent of patient or her family
- Biopsies taken in 1950s – prior to IRBs

- *Are we in a similar situation today with GIS*?

  Are we collecting GIS data in an era when technology is moving faster than regulation? (IRBs are not yet fully aware of the many possible implications of geospatial data, and in many instances, proper policies are not yet in place to protect this type of data we are collecting).

GIS

- Unique circumstances and considerations
- Several types of protectable data
  - Personalized geo-referenced data
  - Address: home, street, census tract/zip, city, state, country.
  - Sociodemographic: average family income (from census data), race, ethnicity
  - Links/web search: phone number, family members, personal background, political affiliations, criminal history, medical history, etc.
  - GPS: location, purchasing patterns, etc.

Still evolving field…

- Most IRBs do not yet fully grasp implications of GIS-based research
- Onus will remain on research to conduct ethical research and handle data in ethical, proper, protected manner
- More questions than answers
- Draw on lessons from history/biomedical research as we begin to formulate and standardize how IRBs should regulate GIS-based research

Thank you!