Research Ethics and Your Summer Student Research

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Origin of human ethics

• Nuremberg Code
  • Stems from the military tribunal proceedings against 23 physicians who participated in Nazi programs to conduct medical experiments on concentration camp prisoners
  • Declaration in 1948 – “The voluntary consent of the human subject is absolutely essential”
  • The first international statement on human ethics
  • Basis for most ethics policies

Principle #1 – Voluntary consent
Tuskegee syphilis “experiment” by the US Public Health Service

- In 1932 enrolled 600 black men from Tuskegee, Alabama in a trial – 399 had previously acquired syphilis (which had no cure at the time of initiation of this study)

- Purpose was to determine by autopsy what syphilis does to the human body

- Were NOT offered treatment in 1947 when penicillin was known to be an effective treatment for the disease (and actively prevented patients from seeking treatment outside of the study)

- This was uncovered in 1972 – 59 relatives contracted this treatable disease

Principle #2 – Cannot deprive anyone of standard of care
Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
THE ASSOCIATE PRESS

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 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. Morin 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 1932 with about 400 black men.
Guatemala gonorrhea study

- 1,300 Guatemalans were infected with gonorrhea in 1946-68 and only ~half were treated with Penicillin
- Resulted in at least 83 deaths
- Discovered in 2005 by a history professor (Susan Reverby) while investigating the Tuskegee study
- Resulted in an apology by the US in 2010

Principle #3 – Cannot introduce/induce disease
HeLa Cells

- Oldest and most commonly used cell line in the world
- Derived from cervical cancer cells from Henrietta Lacks, who died in 1951
- Researchers used her cells without her permission
- The full sequence of her cells was published without the knowledge of her family (NIH worked with family to have a special committee to “hold” the sequence data)

Principle #4 – Cannot use any samples from anyone without their permission
David, the “Bubble Boy” (1971-1984)
(X-linked SCID)

Principle #5 – Ethical standards should evolve
Why do we need to have ethics approval?

• It is the right thing to do

• The University of Alberta could forfeit around $1 billion in federal funding if we are found to allow either animal or human research to proceed without prior ethics approval.

• Unapproved research must be discarded – numerous papers without proper ethics approval have been retracted.
Ethics approvals

• Any research that involves humans or animals requires ethics approval

• It is the responsibility of your supervisor to obtain all appropriate approvals – but it is YOUR responsibility to ensure that approvals have been obtained

• You must receive specific and appropriate training if your work involves an area that requires approval

• For further information see www.reo.ualberta.ca
Human ethics – what requires approval?

- **Just about everything that uses human samples or human subjects**
- Research involving **ANY** human samples (tissue/blood/urine/toenail clippings)
- The country of origin does not matter – approval must be obtained through UofA ethics boards
- Cultured material generated from human samples (exclusion – established cells from ATCC)
- Chart reviews
- Clinical trials
- Surveys
The Research Ethics Office (REO) provides effective, integrated support for and administration of all aspects of the ethics review and approval process for research involving human participants and research, teaching and testing involving animals.

The REO website contains information about ethical review at the University of Alberta, including:

- institutional, national and international guidelines for the ethical conduct of research with human participants and animal subjects.
- the lifecycle of an ethics application – When is ethics review required? How does the process work? Where do I submit an application and how do I receive approval?
- how to sign up for training – both for ethics in general and how to use the online submission system.

For guidance documents and technical assistance for using the Research Ethics Management Online system, please visit the Education, Training and User Support section of our website.

**NEW** Effective Friday, 1 April 2016, all NEW cancer-related ethics applications must be directed to the Health Research Ethics Board of Alberta - Cancer Committee (HREBA:CC)

"Cancer-related Studies" mean studies primarily focused on the study of:
Animal ethics – what requires approval?

• Any research with any non-human vertebrate and any living invertebrate of the class of cephalopoda

• You cannot “borrow” live animals from another lab to euthanize or use for any experimentation

• If you receive samples from another lab that has euthanized the animal, this is allowed as long as they have approval and are willing to allow you to mention this approval in any publications (i.e. should be a collaboration)
Principles of animal research (the three Rs)

• **Replace** the use of animals with alternative approaches

• **Reduce** the numbers of animals used – requires careful planning

• **Refine** the way experiments are carried out to minimize pain and discomfort
Personal responsibility and integrity in research

- All individuals conducting research at the University of Alberta are responsible for the integrity of that research
- Scientific misconduct must be reported
- It might be tempting to “fudge” your data to please your supervisor – DON’T DO IT
- Scientific misconduct is almost always uncovered (usually the next student in the lab cannot reproduce the experiment)
Personal responsibility and integrity in research

- Be a “good citizen” of the lab/research group
- Be fully responsible for your actions
- Keep careful records as required by your supervisor
Authorship

• **Who should be an author?**

• No hard rules, depends on:
  • Field
  • Journal
  • Supervisor – final decision rests with your supervisor

• **General guidelines:**
  • If you just followed a protocol that somebody else gave you, you should be acknowledged for your good technical expertise, but you are not an author.
  • If you just provided a reagent, you should be thanked for your generosity, but you are not an author.
Authorship

- You may or may not be included as an author on any manuscript submitted that includes your data.
  - Data collection does not necessarily result in authorship
  - Some journals require an intellectual contribution for authorship
  - Can you explain the content of the paper – before it is written?

- The work that you produce is with your supervisor and your supervisor is an author on any publications stemming from your work
  - You cannot submit your work for publication without the knowledge of your supervisor
  - Lab notebooks are the property of the laboratory
  - Your supervisor must be included as an author on your Summer Student Research Day abstract
Personal responsibility and integrity in research

- Discovery should be your primary driver for doing research
- There is nothing like the thrill of discovery
- No matter how small your discovery, you are contributing to knowledge for the betterment of society
Questions or concerns

Contact the Office of Research – 213 HMRC

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