Research Ethics and Your Summer Student Research

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(For Hanne Ostergaard, PhD, Associate Dean Research, Graduate Programs)
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
Herman Shaw, one of the last survivors of the Tuskegee study, raises his arms with praise as President Bill Clinton apologizes for the infamous experiment. (Susan Biddle/Washington Post)
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 DNA 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)

- Born with severe combined immunodeficiency
- Went directly into a “bubble” after delivery, which was meant to be temporary until a cure was found
- He lived most of his life in “bubble” and died from complications from a bone marrow transplant
- Procedure received ethical approval – would it be approved today?

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 published by various authors around the world have been retracted because of insufficient or inappropriate ethics approval.
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 before you begin your studies

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

• For further information see uab.ca/reo
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)
• All work performed by UofA employees/students must be obtained through UofA ethics boards – even if it was approved by collaborators at another institution
• 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?
- training and resource materials for research ethics requirements and using the online system.

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

DO I NEED RESEARCH ETHICS APPROVAL?
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.
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.
  - Can you explain the content of the paper – before it is written? – if not, you may not have contributed enough to be an author.
Authorship

- 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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