


Research Ethics and Your Summer Research

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(Content based on presentation by Dr. Hanne
Ostergaard (mostly) and Dr. Luis Schang (some))

Talk outline

- ▶ Why do we need ethics approval for human and animal research?
 - Origins of ethics requirement.
 - ▶ What research needs ethics approval?
 - Human
 - Animal
 - ▶ Personal responsibility and integrity in research.
 - Being a good lab citizen
 - Authorship
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Why do we need ethics approval for research?

- ▶ Origins of ethics approval
- ▶ Nuremberg code (lists 10 key points)
 - Originates from atrocious experiments on humans in concentration camps during WWII by the Nazis.
 - Declaration in 1947 – “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 “observe the natural history of untreated syphilis”
 - Including autopsy
- NOT offered treatment in 1947 when penicillin was proven to be an effective treatment for the disease
 - active prevention of patients seeking treatment
- This was uncovered in 1972 – 59 relatives contracted this treatable disease

Principle #2 – Cannot deprive anyone of standard of care

July 26, 1972

The New York Times

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

By JEAN HELLER
The Associated Press



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 STI study

- Trial funded by United States Public Health Services
- 1,300 Guatemalans were infected with STIs (syphilis, gonorrhea, others) in 1946–48
 - ~half were treated with penicillin
- Resulted in at least 83 deaths
- Great lengths to cover up the trial
- Resulted in an apology by the US in 2010

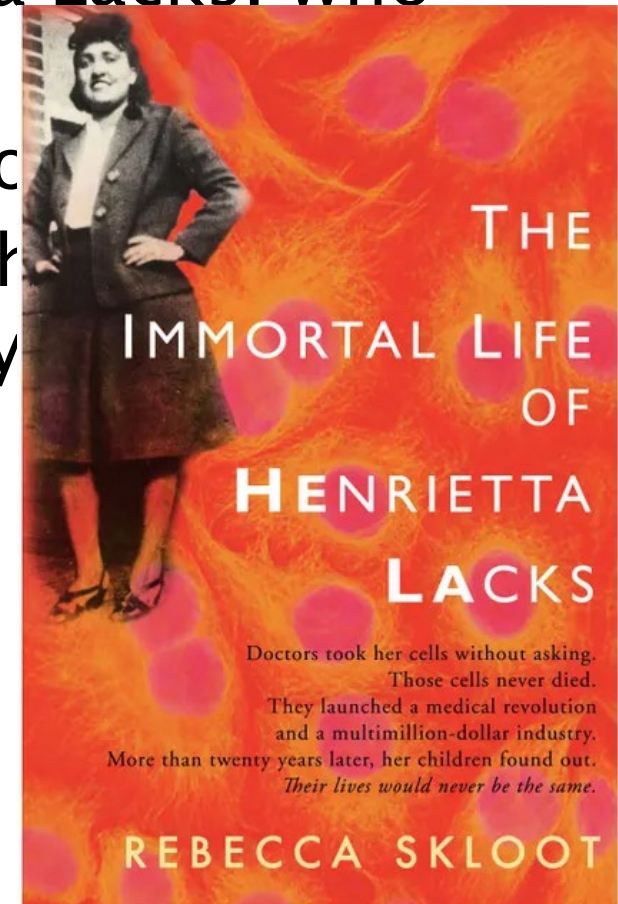
Principle #3 – Cannot introduce/induce disease



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 with knowledge of her family (NIH worked with family 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 ethics approval for research?

“The Nuremberg Code constitutes one of the most important milestones in the history of medicine, providing for the first time a proper framework for research on human subjects. **Sadly, this milestone was not a voluntary, precautionary measure resulting from enlightened humanity, it only came into existence in the aftermath of dreadful Nazi atrocities.**”


Markus Müller, President (“Rector”) of the Medical University of Vienna

Need rules/standards/approvals in place because we can't assume people will behave ethically/humanely.

Why do we need ethics approval for research?

- 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
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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
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Research Ethics

[Do I need research ethics approval?](#)

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Research Ethics

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What requires approval? Human Ethics

- ▶ **Everything that uses human samples or human subjects**
 - Research involving ANY human samples (tissue/blood/urine/ toenail clippings)
 - All work performed by U of A employees/students must obtain approval through U of A ethics boards – even if it was approved by collaborators at another institution
 - Chart reviews
 - Clinical trials
 - Surveys
 - Cultured material generated from human samples (exclusion – established cells from commercial sources e.g., ATCC)


What requires approval? Animal Ethics

- ▶ Any research with any animal
- ▶ 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)

“Animal” *Any living non-human vertebrate and any living invertebrate of the class of cephalopoda, including free-living and reproducing larval forms, used for research, teaching, breeding, or testing purposes at the University.*

(UAPPOL)

Principles of animal research (the three Rs)

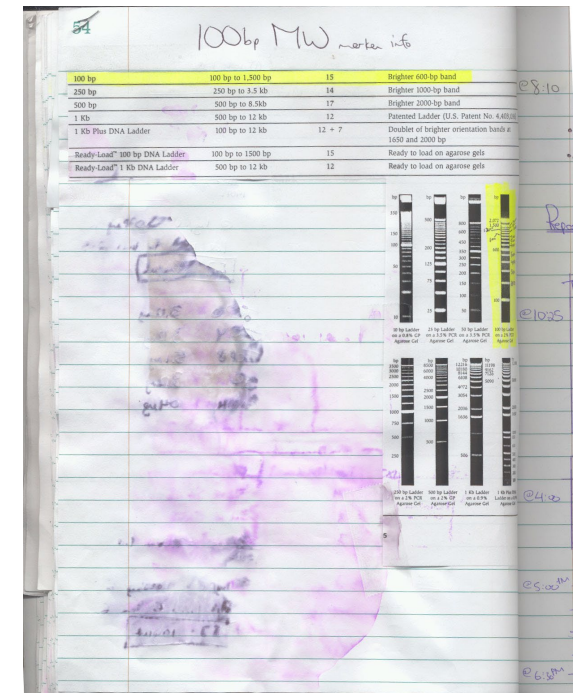
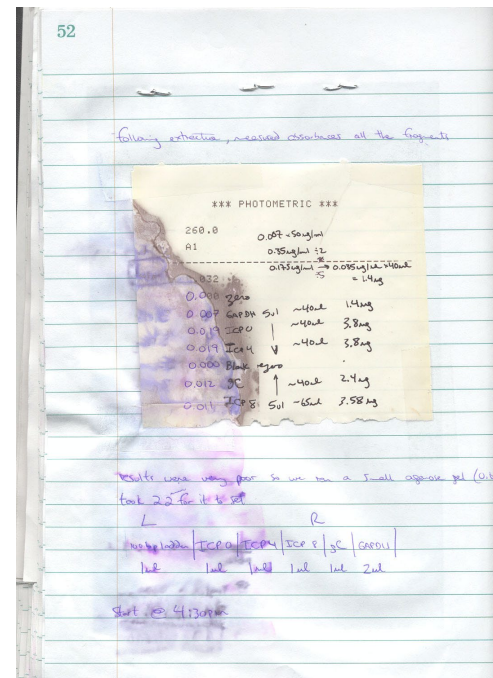
- ▶ Replace the use of animals with alternative approaches
 - ▶ Reduce the numbers of animals used – requires careful planning
 - ▶ Refine the way experiments are carried out to minimize pain and discomfort
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Personal responsibility and integrity in 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—document your experiments so they can be repeated. ASK what the expectations are.
 - Date
 - Purpose
 - Procedures
 - All raw data
 - Use ball point pen!
- ▶ Lab books remain in the lab




Authorship

- ▶ Who should be an author?
 - No hard rules, depends on:
 - Field, Journal, Supervisor – final decision rests with your supervisor
- ▶ International Committee of Medical Journal Editors recommends meeting the following 4 criteria:
 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
 2. Drafting the work or revising it critically for important intellectual content; AND
 3. Final approval of the version to be published; AND
 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.


Authorship

- ▶ General guidelines:
 - Did you follow a protocol that somebody else gave you?
 - acknowledged for technical expertise, not an author.
 - Did you make a reagent?
 - thanked for your generosity, 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 approval of your supervisor
 - ▶ Your supervisor must be included as an author on your Summer Student Research Day abstract
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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
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Questions or concerns

- ▶ Talk to your supervisor
 - ▶ Review the uab.ca/REO website
 - ▶ E-mail me at eleslie@ualberta.ca
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