

The New York Times

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

By JEAN HELLER
The Associated 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 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.

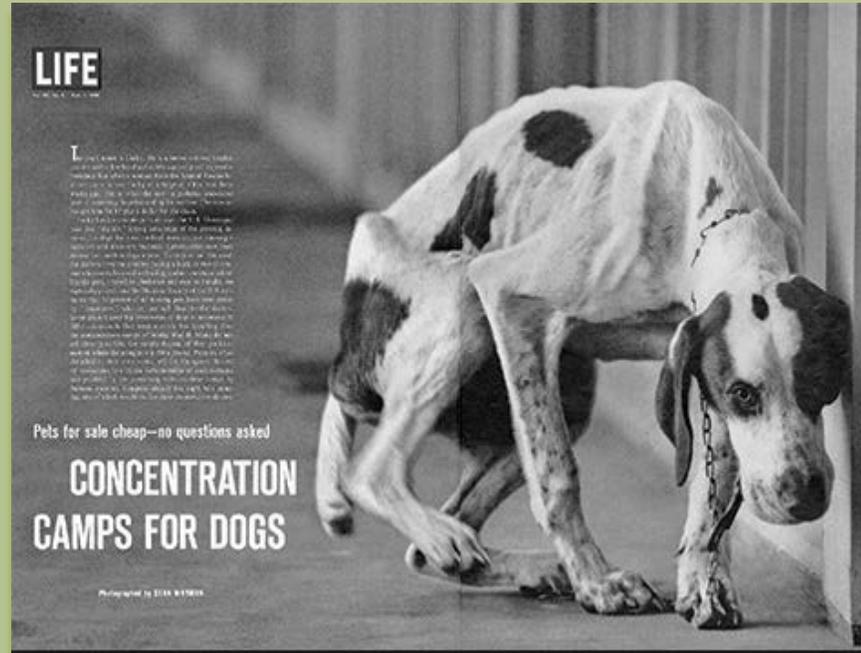
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

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 1932 with about 600 black men,



Congress investigates air leak, possible safety lapses at CDC lab

June 21, 2012 | By Brian Todd and Dugald McConnell, CNN

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It's a highly secured, sophisticated research lab studying deadly diseases such as bird flu, monkeypox, tuberculosis and rabies.

It's in a facility called Building 18, which cost taxpayers \$214 million.

And now, the Biosafety Level 3 lab at the Centers for Disease Control and Prevention in Atlanta is also the subject of a congressional investigation after a potentially dangerous airflow leak at that lab, CNN has learned.

The leak occurred on February 16, when air flowed the wrong way out of a germ lab into a clean-air corridor, rather than through the powerful HEPA filter that cleans the air, congressional sources and CDC officials said. Visitors touring the facility were in the clean corridor when they observed a puff of air being pushed out from the lab through a slot in a door window.



THE HISTORY OF RESEARCH PROTECTIONS

MELANIE LOCHER, B.S., CIP



THE UNIVERSITY OF VERMONT'S OVERSIGHT COMMITTEE'S

- Institutional Review Boards (IRB)
 - Human Subjects Protections (medical and behavioral)
- Institutional Animal Care and Use Committee (IACUC)
 - Vertebrate Animal Research
- Institutional Biosafety Committee (IBC)
 - Ensuring the safety of researchers working with infectious agents





HUMAN SUBJECTS RESEARCH

University of Vermont and The UVM Medical Center are involved in pioneering behavioral and biomedical research and are committed to assuring all research activities are conducted in a manner promoting the rights and welfare of the participants.





WHY IS RESEARCH SO HEAVILY REGULATED?

Nazi War Crimes – Nuremberg
Trials (1945-1946)

20 German physicians and 3 Nazi
officials were charged with crimes
against humanity for conducting
research procedures on
concentration camp prisoners
without consent.

NAZI HUMAN EXPERIMENTATION

- Experiments resulted in death, trauma, disfigurement or permanent disability, and are considered examples of medical torture.
 - Development of new weapons
 - Aid in the recovery of military personnel
 - “cure” homosexuality
 - Twin experiments
 - Freezing
 - Sterilization
 - Bomb experiments
 - High altitude
 - Malaria

*results of the trial horrified the world and led to the creation of the Nuremberg Code. Research ethics for human expiration in medicine.



**Hohenlychen
Sanatorium**

- The experiment began with 600 black men, mostly poor and uneducated, from Tuskegee, Ala., an area that had the highest syphilis rate in the nation at the time
- 399 of the group had syphilis and never received deliberate treatment for the venereal infection.
- A control group of 201 had no syphilis and did not receive any specific therapy.
- As incentives to enter the “program”, the men were promised free transportation to and from hospitals, free hot lunches, free medicine for any disease *other than* syphilis and free burial after autopsies were performed.

TUSKEGEE STUDY - NEW YORK TIMES, 1972



WHAT WENT WRONG?

- The Tuskegee Study began 10 years before penicillin was found to be a cure for syphilis and 15 years before the drug became widely available.
- The men were never given adequate treatment for their disease.
- Even when penicillin became the drug of choice for syphilis in 1945, researchers did not offer it to the subjects.



A MORAL AND ETHICAL NIGHTMARE

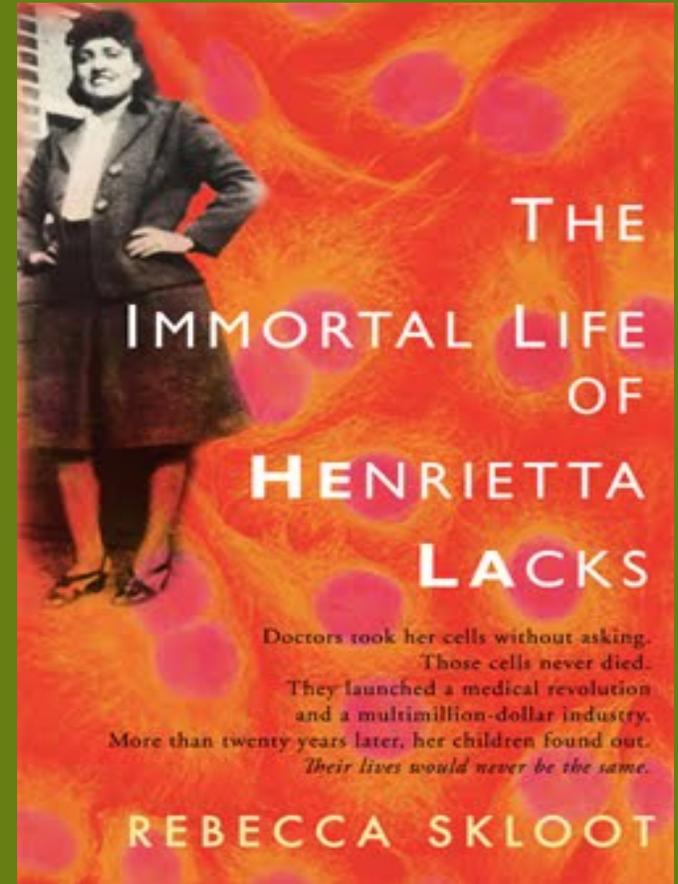
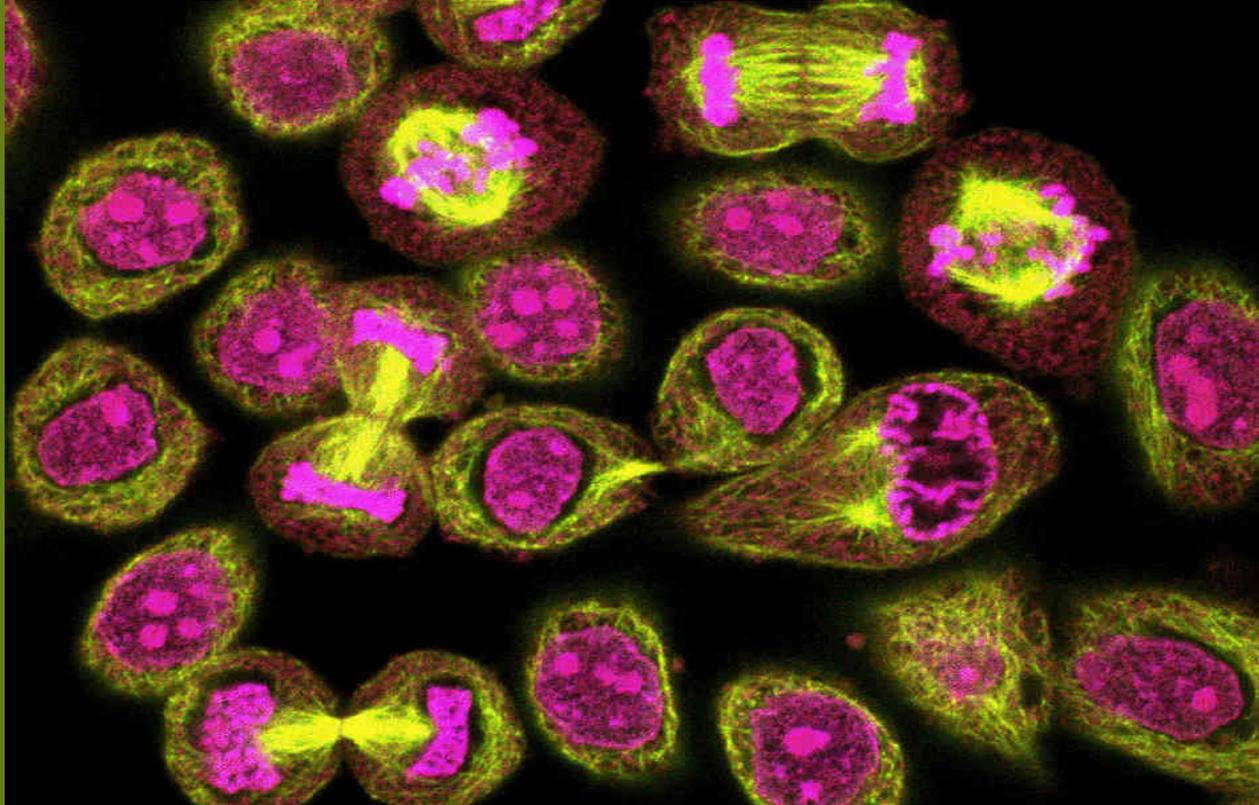
- Syphilis left untreated can cause bone and dental deformations, deafness, blindness, heart disease and deterioration of the central nervous system.
- By 1969 seven participants had died as a direct result of untreated syphilis.
- There was no evidence that researchers had informed them of the study or its real purpose.
- The men had been misled and had not been given all the facts required to provide informed consent.

PREVENTING A REPEAT OF MISTAKES

- In 1974, the National Research Act was signed into law, creating the [National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research](#). The group identified basic principles of research conduct and suggested ways to ensure those principles were followed.
- Researchers must get voluntary consent
- Studies must be reviewed by Institutional Review Boards (**That's us!**) which read study protocols and decide whether they meet ethical standards.

Official apology by President Clinton in 1997





HENRIETTA LACKS

- 1951- Henrietta went to Johns Hopkins for treatment of her aggressive adenocarcinoma of the cervix (dies later in 1951)
- Tissue sample taken without consent – given to Dr. George Gey
- First human cell line developed – HeLa cell line
- Used by researchers around the world
 - Studies with zero gravity in outer space, aided in the development of the polio vaccine, leukemia and AIDS
- Genome sequenced in 2013



WHAT WENT WRONG

- Tissue was taken without her consent
- The cells were not *de-identified*
- Millions of dollars made for companies but the family has received little to none

VERTEBRATE ANIMAL RESEARCH

- The Institutional Animal Care and Use Committee is UVM's central review body for matters relating to the humane care, use and treatment of animals related to research, testing and teaching.



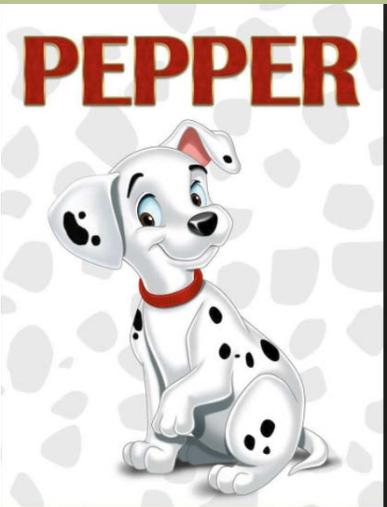
“THE LOST PETS THAT STRAY TO THE LABS”

SPORTS ILLUSTRATED 1965

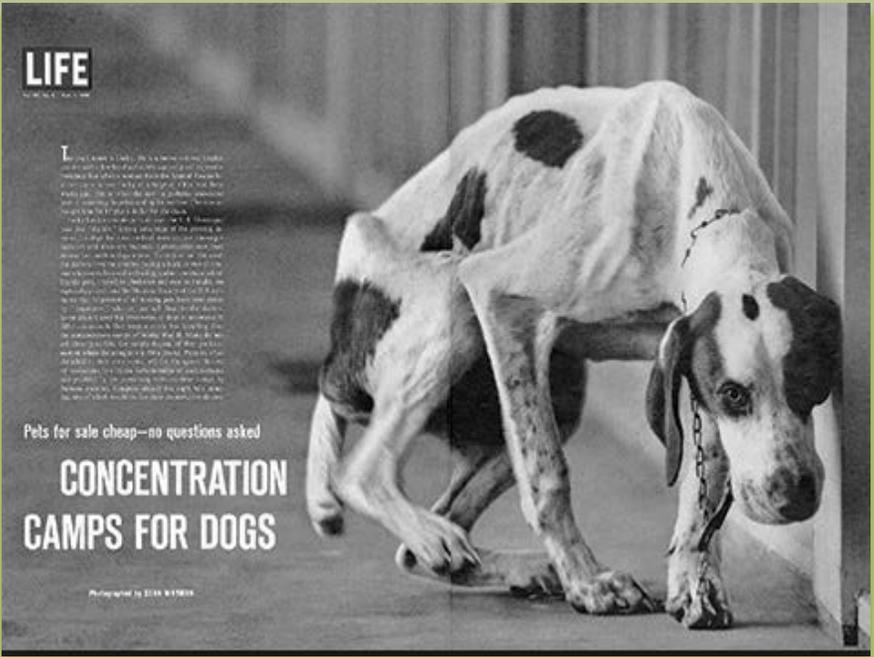
- Pepper the Dalmatian
- June 22, 1965 didn't come back to the PA farm
- Pepper appeared with a known dognapper named Jack who sold animals to hospitals for research.
- Eventually Pepper's body was found Montefiore Hospital in New York City.
- Medical researchers had tried to implant her with an experimental cardiac pacemaker, but the procedure went awry, and she died.



Julia and Peter Lakavage



- Pet dogs were being “dog napped” and sold for animal experiments
- Animals were chained to wooden boxes and left out in the cold to feed on frozen entrails.



“Concentration camp for dogs”
Life magazine 1966

1966 LABORATORY ANIMAL WELFARE ACT (LAFA)

- Public outcry was so great it led to the 1966 Laboratory Animal Welfare Act.
- This act licenses dealers, exhibitors and breeders of animals, regulates research facilities that use animals, lists standards for the humane care and treatment of animals and regulates the transportation of animals.
- Developed 8 areas of minimum standards
 - I. Housing
 - II. Feeding
 - III. Watering
 - IV. Sanitation
 - V. Shelter
 - VI. Separation of Species
 - VII. Ventilation
 - VIII. Adequate Vet Care



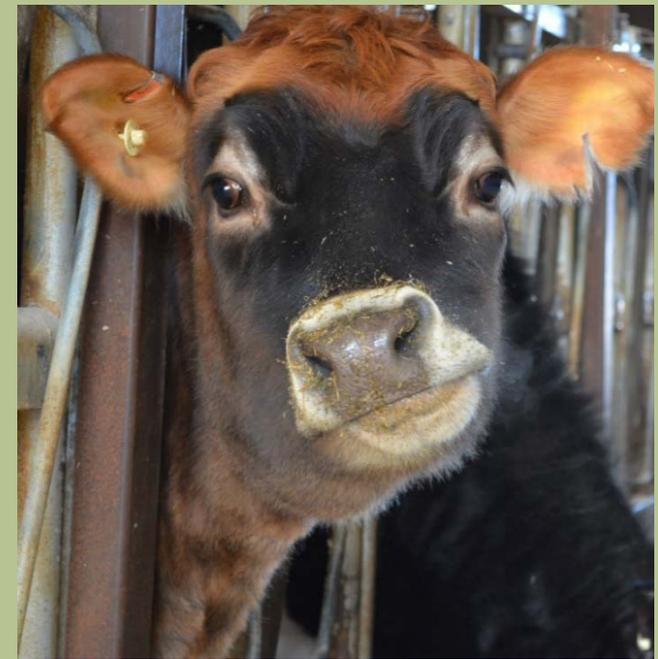
1970 ANIMAL WELFARE ACT

- LAWA changed to AWA
- Extension into the laboratory
- Report number of animals by pain categories
- Require appropriate use of anesthetics
- Included standards for animal transport
- Include all warm blooded except those excluded by the Sec of Ag



1985 ANIMAL WELFARE ACT

- Establishment of IACUC **(That's us!)**
- Assign responsibility to Institutional Official
- Review of protocols
- Semiannual program review & inspection
- Search for alternatives to painful procedures
- Personnel qualifications
- Environmental enrichment for NHPs
- Exercise for dogs





- AWA is now applied to every dog, cat, monkey, rabbit, hamster, and guinea pig in federally funded labs.
- The AWA specifically exempts birds, mice and rats used in research as well as agricultural animals that are used for agricultural production. The Act also exempts horses that are not used for research purposes.
- The United States Department of Agriculture (USDA) is the government agency that is responsible for the enforcement of this act.
- If noncompliance is found this could result in a loss of funding to the institution



BIOSAFETY OVERSIGHT

The University of Vermont (UVM) is committed to minimizing the risks to faculty, staff, students, the public, the facilities, and the environment while using biohazardous materials during research at UVM.

The Institutional Biosafety Committee (IBC) is responsible for ensuring that the use of biohazardous materials in research is done safely.



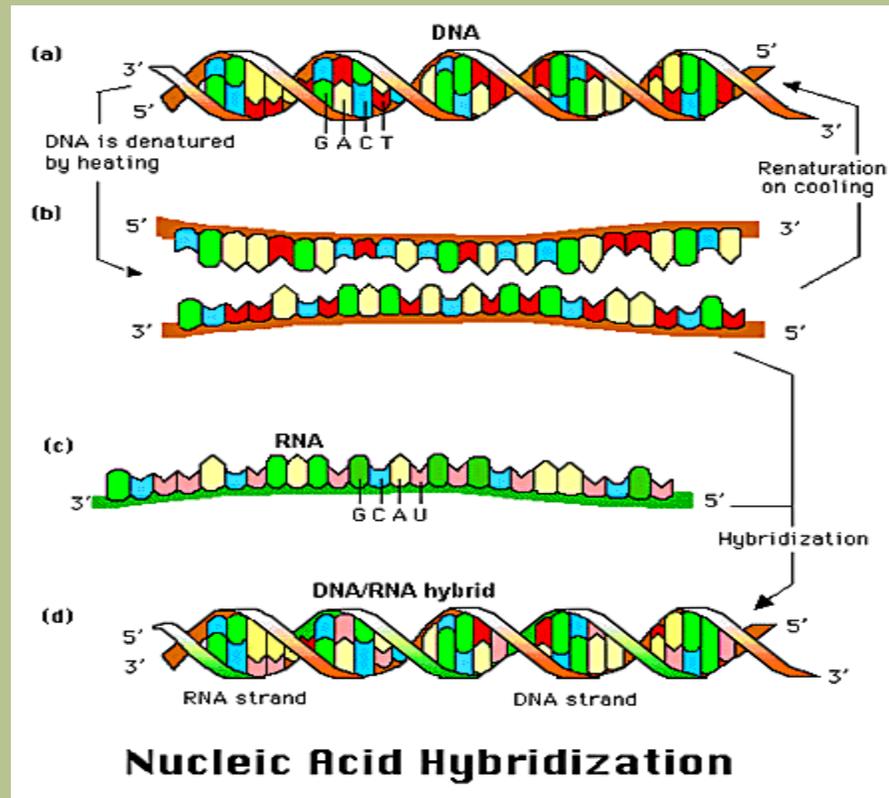


What is a Biohazard?

An agent of biological origin that has the capacity to produce harmful effects on humans; i.e. microorganisms, toxins and allergens derived from those organisms, and allergens and toxins derived from plants or animals.

WHAT BIOHAZARDOUS MATERIALS DOES THE IBC REVIEW?

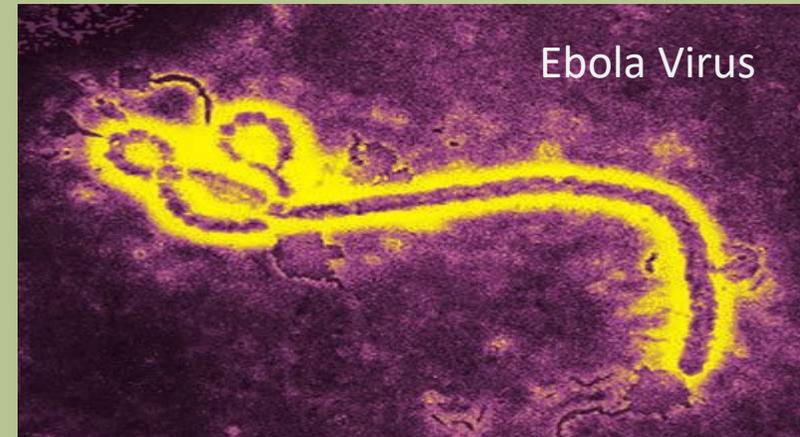
Recombinant DNA – molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication.



WHAT BIOHAZARDOUS MATERIALS DOES THE IBC REVIEW?

Select Agents - Pathogens and toxins considered to have the potential to pose a severe threat to human, animal, or plant health and safety.

- Ebola virus
- Ricin
- 1918 pandemic influenza virus



*UVM currently does not have any IBC protocols or labs working with Select Agents

WHAT BIOHAZARDOUS MATERIALS DOES THE IBC REVIEW?

Infectious Biological Agents – present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment.

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human blood, blood products, tissues, and certain body fluids when used in conjunction with infectious agents or recombinant or synthetic nucleic acid molecules.
- Cultured cells and potentially infectious agents these cells may contain.
- Clinical specimens.
- Infected animal and animal tissues.

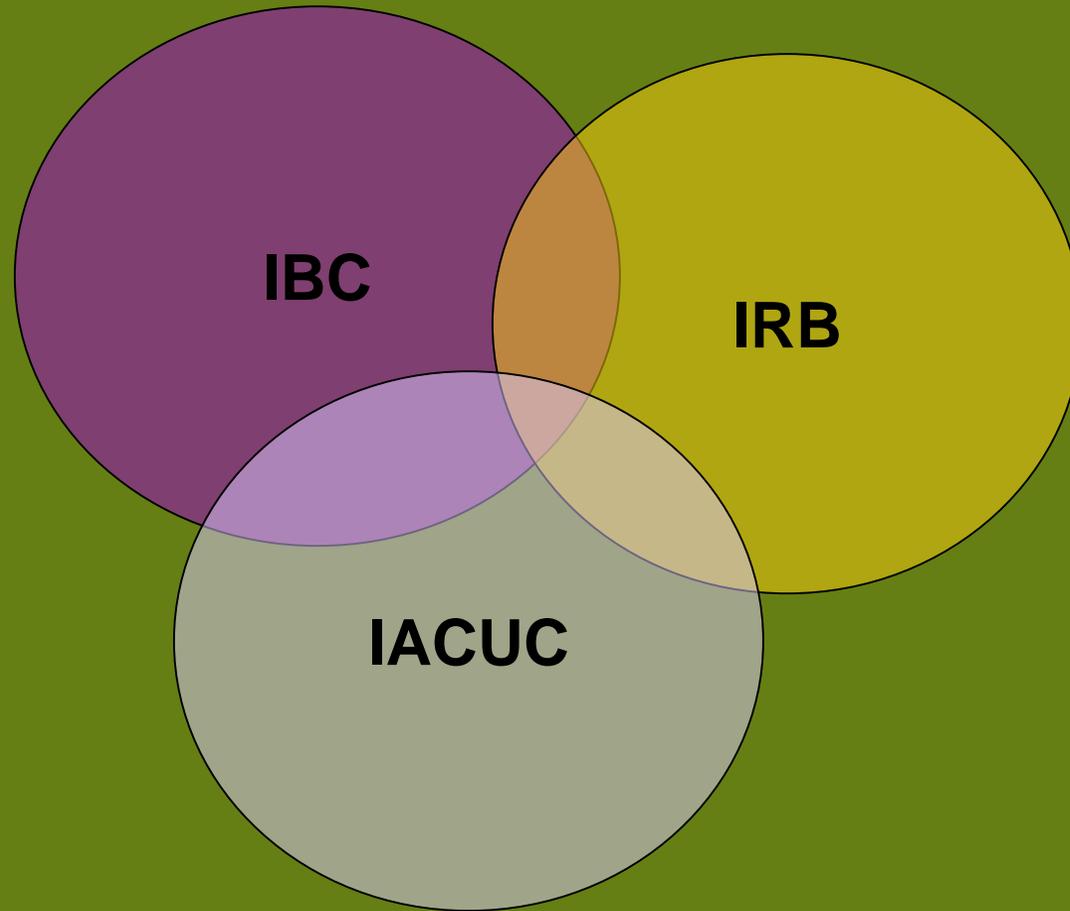


WHAT BIOHAZARDOUS MATERIALS DOES THE IBC REVIEW?

Biotoxins - a poisonous substance that is a specific product of the metabolic activities of a living organism and is usually very unstable, notably toxic when introduced into the tissues, and typically capable of inducing antibody formation.

- Behave like a chemical toxin (not infectious)
- Can be produced by bacterial or fungal fermentation or rDNA
anthrax, botulism, small pox

TB Virus



THE RESEARCH PROTECTIONS OFFICE SUPPORTS THE INSTITUTION'S CONDUCT OF SAFE AND ETHICALLY SOUND SCIENTIFIC RESEARCH INVOLVING HUMAN PARTICIPANTS, VERTEBRATE ANIMALS AND BIOHAZARDS.