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# The ABCs of Research Compliance and Ethics

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Research Compliance and Ethics

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## Ethics

Norms for **conduct** that distinguish between **acceptable**  
and **unacceptable behavior**



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**“Research ETHICS”** refers to a diverse set of values, norms, and institutional regulations that help constitute and regulate research activity

### General Summary of Some Ethical Principles

- Honesty
- Objectivity
- Integrity
- Carefulness
- Openness
- Respect for Intellectual Property
- Confidentiality
- Respect for Colleagues
- Competence
- Legality
- Animal Care
- Human Subjects Protection



## Possible Test Questions

1. Ethics refers to a diverse set of
  - a) Morals, values, institutional regulations
  - b) Values, state regulations, norms
  - c) Norms, values and institutional regulations
2. Which of these is not an ethical principle?
  - a) Honesty
  - b) Carefulness
  - c) Animal Care
  - d) Respect for Intellectual Property



## Possible Test Questions

1. Ethics can be defined as morals for conduct that distinguish between acceptable and unacceptable behavior
  - a) True
  - b) False

**IRB** *Institutional Review Board*

**IACUC** *Institutional Animal Care and Use Committee*

**IBC** *Institutional Biosafety Committee*

# Research

**Federal Regulations define Research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)]**



# IRB



## History and Ethical Behavior in Research... The Belmont Report

- The 1974 National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission wrote ethical principles for the protection of human subjects, commonly referred to as the "**Belmont Report.**"
- The Belmont Report contains the ethical principles upon which the federal regulations pertaining to the protection of human subjects in research are based.

## Research ETHICS for Human Subjects rests on the following principals found in the Belmont Report:

- *Respect for persons*
- *Beneficence*
- *Justice*

## IRB

## RESEARCH

**Federal Regulations define Research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)]**

**IRB review is required when:**

- A faculty member is collecting data on the number of people that visit the mall*
- A faculty member gives a survey to his class to assess his teaching style*
- A faculty member is conducting research which includes interacting with a living individual*
- A student is surveying other students to determine the best meal on campus*



# IACUC



## Research ETHICS for Animal Use rests on the following principals:

- *Reduce*
- *Replace*
- *Refine*

*(Russell and Burch, 1959)*

## IACUC

### Animal Use

**Animal Use is defined as the proper care, use, humane treatment of laboratory animals produced for or used in research, testing, or teaching.**

**Which animal is NOT covered by the Animal Welfare Act:**

- a) Rabbits
- b) Non-human primates
- c) Chinchillas
- d) Reptiles

## IBC

## IBC

### Biological and Biohazardous Materials

**The ethics of biosafety is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous or detrimental materials.**

**The IBC's general responsibility is to review research involving:**

- a) *rDNA (Recombinant DNA)*
- b) *Biohazardous materials*
- c) *Bloodborne pathogens*
- d) *Chemicals*

## Possible Test Questions

1. What are the three principles from the Belmont Report?
  - a) Justice, Respect for Persons, Magnificence
  - b) Respect for Persons, Justice, Beneficence
  - c) Respect for Persons, Beneficence, Jury Duty
2. Which of these is not reviewable by the IBC?
  - a) rDNA (Recombinant DNA)
  - b) Biohazardous materials
  - c) Bloodborne pathogens
  - d) Chemicals



## Possible Test Questions

Which member of the IRB, IACUC, and IBC bring the perspective of the community?

- a) *Non-scientist*
- b) *Non-affiliated member*
- c) *Attending Veterinarian*
- d) *Biosafety Officer*

What minimum number of members is required for the IACUC?

- a) 5
- b) 6
- c) 4
- d) 7



# RESEARCH MISCONDUCT

“**Research MISCONDUCT**” refers to fabrication, falsification, or plagiarism (*FFP*) in proposing, performing, or reviewing research, or in reporting research results.

Research Misconduct does not include honest error or differences of opinion

## Examples of Research Misconduct

- Making up data that was not obtained – ***fabrication***
- Changing data obtained so the research question is answered favorably – ***falsification***
- Present ideas or findings from others as your own – ***plagiarism***

Research **misconduct** is deemed ONLY when  
researchers  
INTEND TO DECEIVE

However, **unethical behavior** occurs when one  
DEVIATES from ETHICAL PRINCIPLES

Dr. B has just discovered a mathematical error in a paper that has been accepted for publication in a journal. The error does not affect the overall results of his research, but it is potentially misleading. The journal has just gone to press, so it is too late to catch the error before it appears in print. In order to avoid embarrassment, Dr. B decides to ignore the error.

How would you categorize his decision?



# COI



## CONFLICT OF INTEREST

A situation in which a person is in a position to **personally benefit** from an action/decision made in their official capacity (job, position, etc.)

## CONFLICT OF INTEREST



*"Yes, I am employee of the month again. And yes, I'm the one who chooses the employee of the month. And no, I don't see a conflict of interest."*

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*"Try this—I just bought a hundred shares."*

# EXPORT CONTROL

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## EXPORT CONTROL DEFINITIONS

**An export** - any oral, written, electronic or visual disclosure, shipment, transfer or transmission of commodities, technology, information, technical data, assistance or software codes to:

- *Anyone outside the U.S. including U.S. citizens*
- *A non-U.S. individual wherever they are*
- *A foreign embassy or affiliate*

**Foreign National** – an individual who is not a U.S. citizen, a permanent resident alien of the U.S., or a protected individual as defined by 8 U.S.C. 1324b(a)(3)

**Deemed Export** – disclosure or transfer of export controlled items, including technology and information, to a foreign entity or individual **within the U.S.**

## How did export control come about?

These laws have been in existence for many years, however...

**9/11**

## EXPORT CONTROL

Federal laws govern export controls:

- **Department of Commerce** – enforces the Export Control Administration Regulation (EAR)
- **Department of State** – enforces the International Traffic in Arms Regulations (ITAR)
- **Department of Treasury, Office of Foreign Assets Control (OFAC)** – restricts exports and imports through economic sanctions against certain countries

## EXPORT CONTROL

EAR Covers (15 CFR 730-774)

- **Covers dual use items** (civilian and military applications)
- Regulates **items designed for commercial purposes** but which could have **military application** (computers, civilian aircraft, pathogens)
- Covers both the **goods and the technology**
- **Deemed exports**
- **Re-exports** (sending something overseas that is then sent to a third country)

## EXPORT CONTROL

### ITAR Covers (22 CFR 120-130)

- Covers **military items or defense articles**
- Regulates **goods and technology designed to kill** or defend against death in a military setting
- Includes **space related technology** because of application to missile technology
- Includes **technical data related to defense articles** and services

## EXPORT CONTROL

### OFAC Covers (31 Part CFR 500-599)

- Office of Foreign Assets Control
- Regulates the **transfer of items/services** of value to **embargoed nations**
- **Imposes trade sanctions**, and trade and travel embargoes aimed at controlling terrorism, drug trafficking and other illicit activities
- **Prohibits payments**/providing value to nationals of sanctioned countries and some specified entities/individuals
- **May prohibit travel and other activities** with embargoed countries and individuals even when exclusions to EAR/ITAR apply.

## EXPORT CONTROL

### Exclusions/exceptions to export control requirements

- **Fundamental Research Exclusion** - applies to the products, but not the underlying data or documents, of basic and applied research in science and engineering performed by universities **as long as the resulting information is ordinarily published** and shared broadly within the scientific community.
- **Educational Information** - **information commonly taught** for instruction in courses and associated with general scientific, mathematical, or engineering principles
- **Publicly Available** - **information generally accessible to the public**, such as information in libraries, bookstores, open seminars, and published patent information. However, the State Department has determined that information contained on internet sites is not necessarily considered to be in the public domain.

## Possible Test Questions

Which is not a regulatory Export Control Agency

- a) *ITAR*
- b) *FACE*
- c) *EAR*
- d) *OFAC*

Office of Foreign Assets Control (OFAC) covers?

- a) *Regulates the transfer of items/services of value to embargoed nations*
- b) *May prohibit travel and other activities with embargoed countries 4*
- c) *Prohibits payments*



# Q&A