Scientific Ethics

Scientific Ethics

- Research ethics are an essential part of your research career.
- The research you carry out must be honest, accurate and ethical.

Scientific Ethics

- **Research ethics**, defined as the standards of conduct for scientists in their professional endeavors, covers a broad swath of activities from issues on topics such as the use of human subjects in research or the appropriateness of patenting genetically modified organisms to peer review, to one-on-one mentoring in individual laboratories.

Excellent Science, Excellent Ethics

- **Science can be said to be ethical in two different ways:**

♦ **<u>Ethics of the topics and findings (morality):</u>**

✓ Ethicists consider the question of whether science is good or bad, especially in specific fields of science such as biomedical and other research where human or animal subjects are involved. Also,

✓ Groups with strong beliefs raise ethical questions when possible uses of the findings or the process for doing the science are in opposition to their tenets.

✓ Scientists themselves may raise moral or ethical issues, understanding the potential for harm related to the research process or outcome.

Excellent Science, Excellent Ethics

♦ **Ethics of method and process (integrity):**

- ✓ It addresses the nature of the design, the experimental procedures, and the reporting of the research effort.
- ✓ The assumption of scientific integrity in carrying out the processes of science is basic to trust among scientists, between society and scientists, and to the credibility of scientific results.
- ✓ The research record is important because it is by examining the inputs to a piece of scientific research that scientists with similar expertise can judge the competence of the research design and the credibility of the findings.

Scientific Integrity

- **<u>Research has to have four principles:</u>**

1. *Honesty in all aspects of research,*
2. *Accountability in the conduct of research,*
3. *Professional courtesy and fairness in working with others,* and
4. *Good stewardship of research on behalf of others.*

   <u>"the 2nd World Conference on Research Integrity, July 2010"</u>

Scientific Integrity

- Research must never start until it has been accepted and approved by your organization's of ethics committee, to ensure minimal or no adverse effects for the animals / subjects, and you stay within the legal requirements for such research.

Scientific Integrity

- It is essential that the rights and privacy of all human participants in any research you may carry out are protected and,…..
- Your organization's human ethics committee will assist you in ensuring that this happens.
- Even procedures as potentially harmless as **telephone interviews** may have significant impacts on human ethics and thus they require approval.

Scientific Integrity

- As for the **bio/ radiological** aspects of ethics, although, there is a very small percentage of researchers apply such a research, it is an extremely important and these days it even attracts security supervision.
- It is therefore essential, to obtain the approval of your organization's appropriate committees, which may even involve them requiring national approval.

Stakeholders in the Scientific Community

- Those who have the ability to promote scientific integrity and roles to play in oversight of scientific research and in controlling scientific misconduct include:

  ♦ Scientists themselves, who serve not only as practitioners but also as reviewers, colleagues, consumers of other scientists' work, and members of professional associations (Frankel 1993).

  ♦ Editors and publishers of scientific articles, who have an interest in being the first to publish ground-breaking science (and who therefore contribute to the pressure on scientists), but also have an interest in enhancing and maintaining the reputation of their publications and institutions.

Stakeholders in the Scientific Community

♦ Research project managers, who both conduct science and oversee the work of other scientists

♦ Institutional research program officials, who employ the scientists and therefore have direct line responsibility for ensuring compliance with regulatory and contractual requirements and a need to maintain a volume of research that supports those employees and the institutional communications

♦ Officials in federal and other research funding agencies who commission the research and have responsibility for ensuring that the funds are used effectively and provide benefit.

Types of Problematic Behavior:

- A brief review of the resulting categories of possible errors scientists can make and unethical behaviors in which they can engage illustrates that many gray areas exist;
    - ♦ Honest mistakes
    - ♦ Unethical behavior
    - ♦ Noncompliance with legal or contractual requirements
    - ♦ intentional dishonesty (scientific misconduct)

Types of Problematic Behavior

- **Honest Mistakes**
  - ♦ Scientists and their assistants, being only human, can make inadvertent mistakes of various kinds during design, calibration, classification, data entry, and so forth.
  - ♦ Errors in interpretation might also fall into the category of honest mistakes. Honest errors and errors resulting from the sloppy execution of research can be corrected by the scientists themselves – if they discover their own mistakes – as well as by the reviewer or replicate the research.
  - ♦ Thus – mistakes can affect future funding and careers— scientists are likely to take pains to avoid mistakes.

Types of Problematic Behavior

- **Unethical Behavior or "Scientific Misdemeanors"**
  - ♦ Improprieties of authorship, such as duplicate publication of a single set of research results or fractional publication
  - ♦ "Gift" or "honorary" authorship
  - ♦ Incomplete citation of previously published work
  - ♦ Bias in peer review of proposals or manuscripts
  - ♦ Skewed selection of data or results to hide or mask observations that do not fit the author's conclusions.

Types of Problematic Behavior

- **Noncompliance**

♦ Noncompliance generally refers to failures to follow practices dictated by law.

- Researchers are accountable to Institutional Review Committees (IRB) and generally need approval for their studies that involve human subjects and animals, handling dangerous materials -- such as biohazards, hazardous chemicals, the transfer of etiologic agents, and radioactivity-- or in recombinant DNA.

Types of Problematic Behavior

- **Scientific Misconduct**

♦ The **federal agencies (USA)** defined research misconduct as " fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

Prevalence and Significance of Scientific Misconduct

- In 1996, nearly 170 scientists were under suspicion by the federal government for possibly committing scientific misconduct and at least 20 scientists were found to have committed scientific misconduct (Dooley and Kerch 2000).
- The National Institutes of Health (NIH) had close to 100 "active cases" of scientific misconduct and found 17 individuals to have committed scientific misconduct while using NIH research funds.
- The National Science Foundation (NSF) had approximately 70 active cases and found approximately six individuals guilty of scientific misconduct.

Prevalence and Significance of Scientific Misconduct

- An alternative approach to estimating the prevalence of scientific misconduct is to survey scientists themselves.
  - In 1991 the American Association for the Advancement of Science (AAAS) conducted a survey of 1500 scientists. A quarter of those who responded reported that they had witnessed faking, falsifying, or outright theft of research in the past decade (Marsa 1992)

Prevalence and Significance of Scientific Misconduct

- Nevertheless, the perspective of the research community is that given the large numbers of projects funded each year, the rate of scientific misconduct is low.
- This does not mean, however, that scientists, science-implementing organizations, and science-funding organizations do not need to be concerned about scientific misconduct.

Choosing your Publication's Style and Format

- Publication of your research is essential, whichever format you choose.
- However, If you do not publish your research outcomes, no one will ever know of its existence.
- Producing publications is essential to your research effort, as future grants, promotion, and, also,
- job opportunities will depend upon the substantial high-quality research outputs documented in your CV.

Choosing your Publication's Style and Format

- It is your decision to publishing in international formats in English compared with national formats in your own language.
- your decision to try to publish locally or internationally is whether to publish with an international publisher of journals and books or with a local potentially lesser known publisher.
- The decision of both choices is based on the quality of the work you have done and on your research discipline area.

Choosing your Publication's Style and Format

- you may alternate between these strategies depending on the circumstance prevailing at the time.
  - For examples;
  - ❖ Are you trying to complete and publish some work before submission of your Ph.D. ;
  - ❖ or before the end of your current post-doc?
  - ❖ Are your research colleagues and Supervisor suggesting that you complete additional work before publishing?
  - ❖ Does your Mentor believe that you should spend time writing a book rather than trying to publish a few journal articles?
- It is up to you to decide on how you commit your most valuable resources, your time and effort.

Choosing your Publication's Style and Format

- If you have to make a choice between the quality and quantity of your publications, always aim for quality whenever possible
- **Quality** is always of prime importance, and it is being focused on more and more.
- Having taken all these points on different publication formats into consideration, journal publication is certainly the most recognized format.

Where to publish??

- **There are a number of factors that you should consider before even starting to write a paper for submission;….**

❑ Whether to send your paper to an open access journal or a journal published by a traditional subscription based publisher. (52).

❑ The journal's prestige and the makeup of the journal's readership; such as *“clarity/coherence/well written”, “thoroughness”, “research method” and “appropriateness to Journal”* ---the quality of the journal

Where to publish??

- It is strongly recommended that you use all available appropriate resources to validate the high quality and impact of your research outputs to your peers.
- What is the speed of acceptance of papers in the journal?
- Is the area of your research similar to that which the journal normally publishes?
- Is the quality of your research really at the level that is typically published in the journal?

Where to publish??

-- **Having identified a journal you wish to submit to, what do you now need to focus on with respect to writing your paper???**

- The major issue in submitting a paper to a journal for publication is to first read, understand and comply with the Instructions to Authors to ensure the most efficient processing and reviewing of your paper, and should be done before you start drafting it.
- Then you start from the Title and Abstract and write a complete draft of the paper.
- Having the core of the paper outlined even in dot points facilitates the writing process.
- Making a complete draft avoids getting stuck on a point that prevents or delays documenting the rest of the paper.
- Often making each section perfect before you do the next section, is usually inefficient.
- obtaining the input of a native English speaker if English is not your first language

Where to publish??

- Author **AID** is a free international research community that helps researchers in developing countries to publish or otherwise communicate their work.
- It also serves as a wider global forum to discuss and disseminate research.
- It is a pioneering program based at the International Network for the Availability of Scientific Publications, supported by the Swedish International Development Cooperation Agency, the Norwegian Agency for Development Cooperation, and the UK Department of International Development.
- It undertakes training workshops on scientific writing, and provides access to a range of documents and practices on best practice in writing and publication.
- The best known text to improve publication skills for established researchers is "How to Write and Publish a Scientific Paper" and the recently published "Writing Scientific Research Articles: Strategy and Steps" is focused on **ECR**s wanting to hone their skills as an author and a mentor, and scientists interested in using English more effectively, as a first or an additional language.

Articles steps!!

- Your title, should contain the fewest possible words that accurately describe the paper‘s content. It should express only one idea or subject and start with a few important words.

- The Introduction should begin with concise description of essential background to the problem, hypothesis or area of scholarly activity being researched.

- Then state the objective of the research and clearly establish the significance of your work, especially in relation to what was previously know about the area.

Articles steps!!

- The Methods section should always be accurate, described in sufficient detail to be able to be fully reproduced, and for quantitative studies, have well documented and appropriate statistical tests.

- Organize your Discussion to go from a specific focus to a general one, and relate your findings to the research literature, to theories, and to practices in your research discipline.

Articles steps!!

- Restate the hypothesis you were testing or scholarly question being addressed and provide answers for questions asked in the Introduction.

- Support your answers with accurate, clear and validated Results. Explain concisely and clearly how your results relate to expectations and to the research literature on the topic.

- Discuss, evaluate and offer reasonable reasons for conflicting results.

Articles steps!!

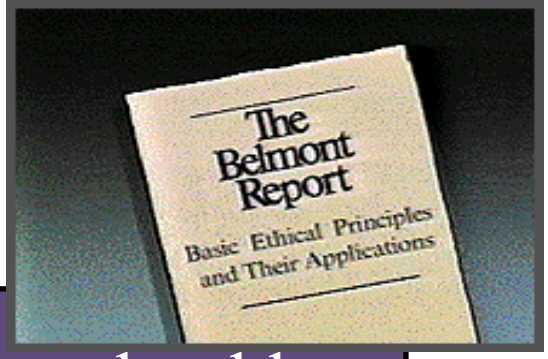
- Discuss any unexpected findings and provide a few recommendations for further research, but do not over extrapolate or make claims that are not definitively confirmed by your results.

- In summary, your paper should describe excellent (novel and innovative) research, be well described and not over extrapolated, with accurate statistics if appropriate, and
- follow a concise logical progression convincing the reader of its quality.

- Abstract and key words are essential.

Research Ethics

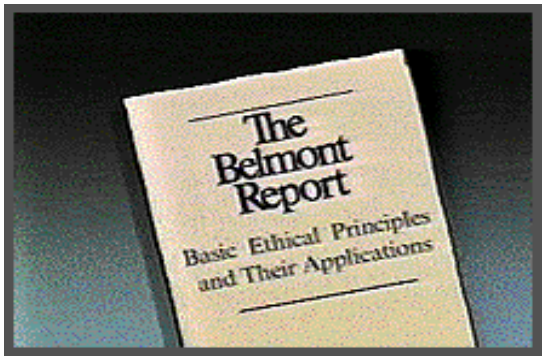
Research Ethics



WHY STUDY RESEARCH ETHICS?

- Knowing what constitutes ethical research is important for all people who conduct research projects or use and apply the results from research findings.

- All researchers should be familiar with the basic ethical principles and have up-to-date knowledge about policies and procedures designed to ensure the safety of research subjects and to prevent sloppy or irresponsible research,----------
  Why!!!!



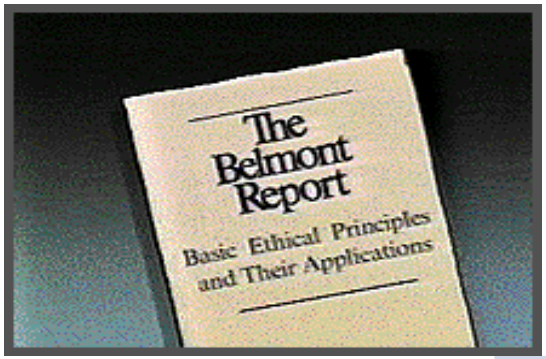
Research Ethics

WHY!

- because ignorance of policies designed to protect research subjects is not considered a viable excuse for ethically questionable projects

Therefore;

- the duty lies with the researcher to seek out and fully understand the policies and theories designed to guarantee upstanding research practices.



Research Ethics

DEFINITION

- Research ethics provides guidelines for the responsible conduct of biomedical research.

In addition

- research ethics educates and monitors scientists conducting research to ensure a high ethical standard.

Research Ethics Guidelines

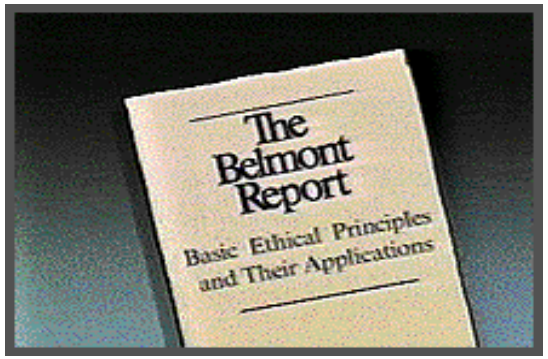
There are ethical guidelines for the conduct of research were developed:

Research participants must voluntarily consent to research participation

Research aims should contribute to the good of society

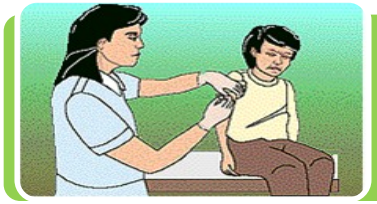
Research must avoid unnecessary physical and mental suffering

Research must be based on sound theory and prior testing



Research Ethics Guidelines

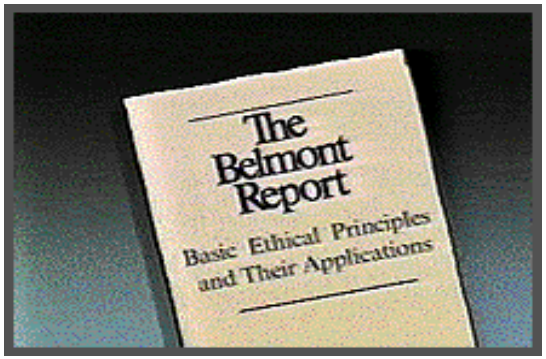
No research projects can go forward where serious injury and/or death are potential outcomes.



The degree of risk taken with research participants cannot exceed anticipated benefits of results

Proper environment and protection for participants is necessary.

Experiments can be conducted only by scientifically qualified persons.



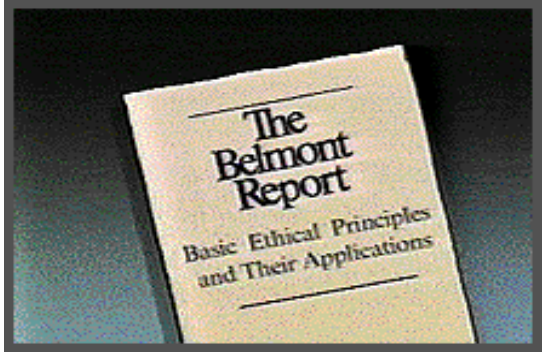
Research Ethics Guidelines

- Human subjects must be allowed to discontinue their participation at any time.

- Scientists must be prepared to terminate the experiment if there is cause to believe that continuation will be harmful or result in injury or death.

- The necessity of using an independent investigator to review potential research projects

- Employing a medically qualified person to supervise the research and assume responsibility for the health and welfare of human subjects.



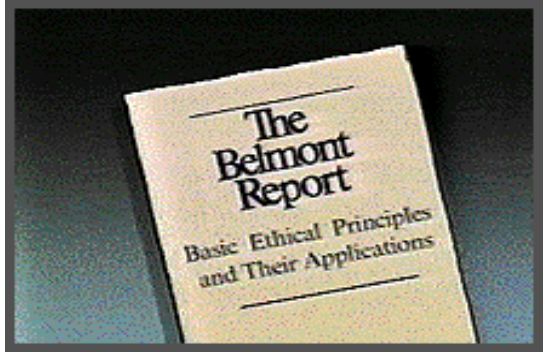
Research Ethics Guidelines

The importance of preserving the accuracy of research results.

Rules concerning research with children and mentally incompetent persons.

Evaluating and using experimental treatments on patients.

The importance of determining which medical situations and conditions are appropriate and safe for research.



Research Ethics Guidelines

The concepts of respect for persons, beneficence, and justice

Applications of these principles in informed consent (respect for persons), assessing risks and benefits (beneficence), and subject selection (justice)

AUTHORSHIP

DEFINITION AND IMPORTANCE

Authorship is the process of deciding whose names belong on a research paper.

In many cases, research evolves from collaboration and assistance between experts and colleagues.

Some of this assistance will require acknowledgement and some will require joint authorship.

AUTHORSHIP

Despite the challenges, to be as authors, coauthors, or acknowledge colleagues, researchers should familiarize themselves with proper authorship practices in order to protect their work and ideas while also preventing research fraud.

AUTHORSHIP

ETHICAL GUIDELINES

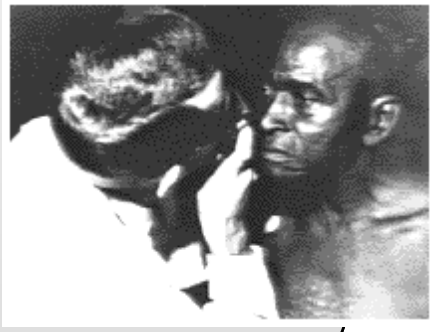
The International Committee of Medical Journal Editors (ICMJE)

is the recognized international expert organization when it comes to guidelines regarding biomedical research authorship.

Their website (**www.icmje.org**) *lists all requirements for authorship, which are quoted as follows:*

AUTHORSHIP

- Authorship credit should be based only on:



1) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;

2) Drafting the article or revising it critically for important intellectual content; and

3) Final approval of the version to be published.

AUTHORSHIP

- Conditions 1, 2, and 3 must all be met.

- Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.

“Can I be a co-author?”

“Sure! But only if you…

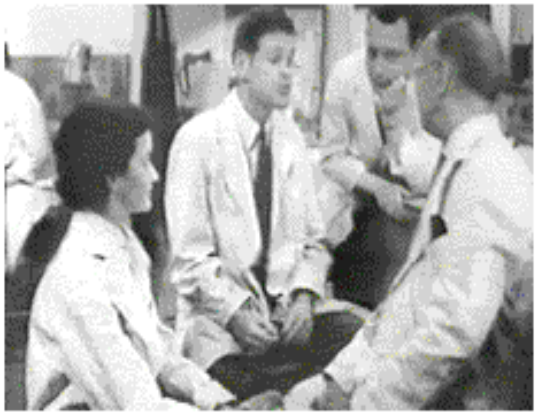
1- • Contributed substantially to the research, AND…

2- • Wrote or revised all or part of the manuscript, AND…

3- • Approved the final version of the entire article.”

- ~ Guidelines from the ICMJE
- website at www.icmje.org

AUTHORSHIP



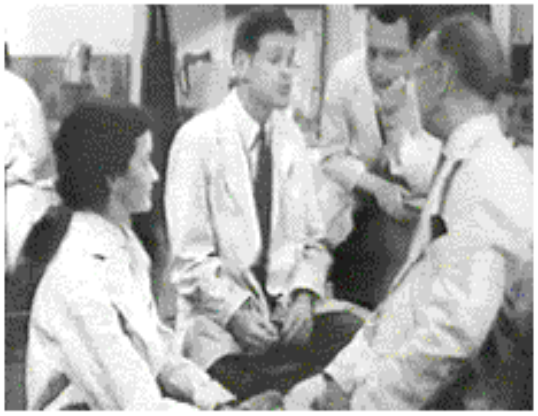
❖All the contributing co-authors of an article must jointly decide the order of the listing of names.

❖The first person listed should be the person most closely involved with the research.

❖The authors should then decide the order of the remaining authors in accordance with the criteria of the publishing journal, and be prepared to answer questions about why the order is as it appears.

AUTHORSHIP

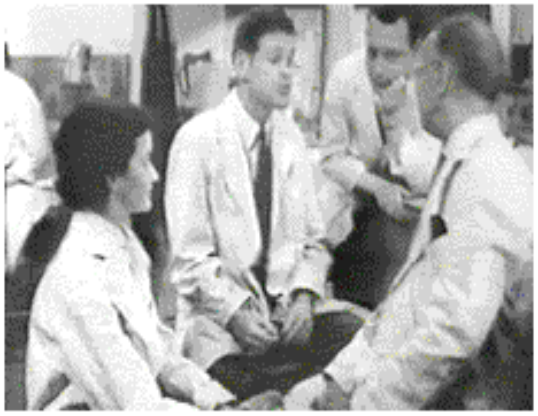
EXAMPLE CASE STUDY



*Query Jamal is a graduate student working under the supervision of professor, Dr.*Kerry….Dr. Kerry is conducting research on tooth decay and has gathered data from hundreds of dental patients. Jamal uses Dr. Kerry's data to analyze a research question that he came up with on his own about tooth enamel erosion. His question is his own idea, but is still based on what he learned about tooth and enamel decay under Dr. Kerry….Jamal's friend, Darcie, helped Jamal design a statistical computer program for data analysis, but did not contribute in any other way to the research.,

AUTHORSHIP

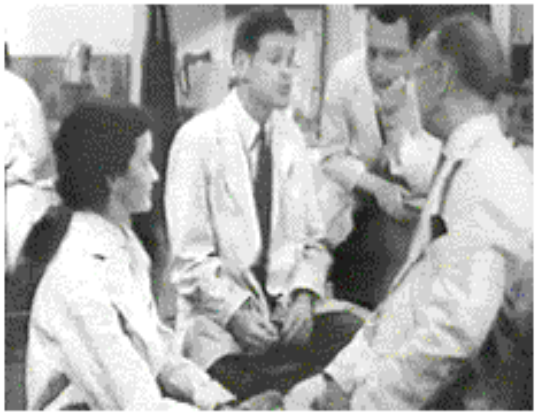
Continue---



When writing up his results, Dr. Kerry helped Jamal write the methods section of his manuscript and reviewed his final results and conclusions as well as the final draft of the entire manuscript. How
should authorship be decided in this case?

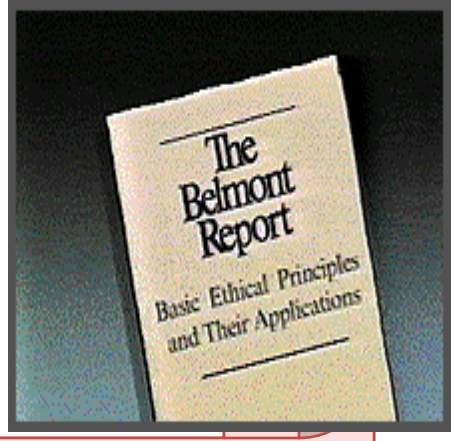
AUTHORSHIP

Answer ----



Jamal should be listed first as the primary author because he is most closely involved in the research project. Dr. Kerry should be listed second as co-author because she meets the ICJME requirements of authorship. Darcie does not meet the criteria for authorship, but she should be acknowledged for her contribution if she so consents.

PLAGIARISM

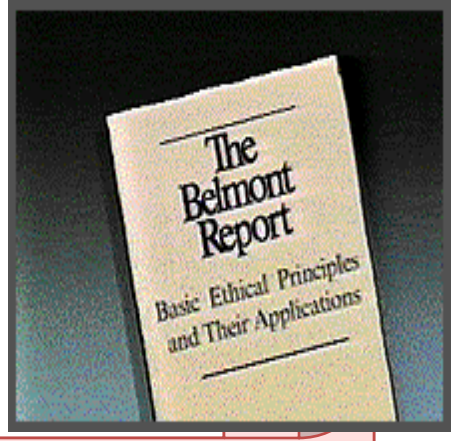


DEFINITION AND IMPORTANCE

Plagiarism is the act of passing off somebody else's ideas, thoughts, pictures, theories, words, or stories as your own.

Plagiarism is both an illegal act and punishable, considered to be on the same level as stealing from the author that which he or she originally created.

PLAGIARISM



Plagiarism takes many forms;

- ✓On one end of the spectrum are people who intentionally take a passage word-for-word, put it in their own work, and do not properly credit the original author.
- ✓The other end consists of unintentional (or simply lazy) paraphrased and fragmented texts the author has pieced together from several works without properly citing the original sources.10,11

PLAGIARISM

ETHICAL GUIDELINES

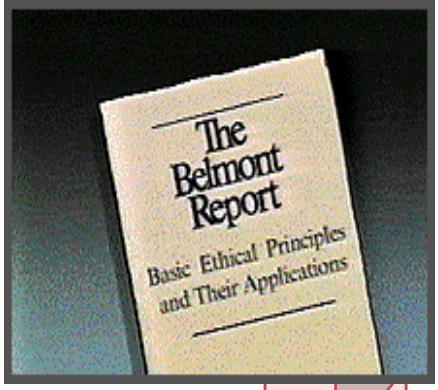
<u>To avoid plagiarism, the Indiana University website provides the following advice;</u>

A researcher preparing a written manuscript should cite the original source if he or she:

- "Quotes another person's actual words, either oral or written;
- Paraphrases another person's words, either oral or written;
- Uses another person's idea, opinion, or theory; or

PLAGIARISM

Continue…….

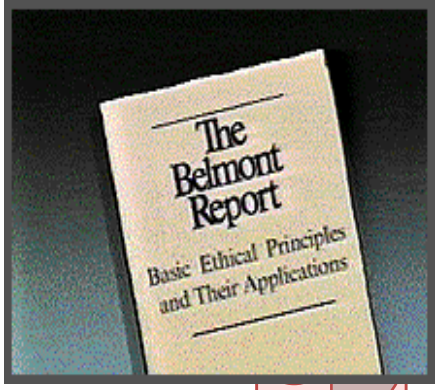


❖Borrows facts, statistics, or other illustrative material, unless the information is common knowledge.”12

❖Using another person’s graphics or text from a web page, an author should ask permission to use the material from the original author or website host. 13

PLAGIARISM

Continue…….



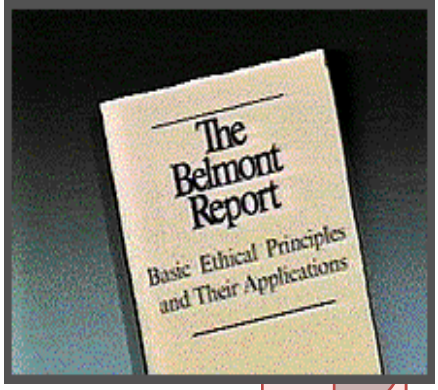
<u>To avoid unintentional or accidental plagiarizing of another person's work, use the following tips from the Northwestern University website:</u>

- ✓Cite all ideas and information that is not your own and/or is not common knowledge,

- ✓Always use quotation marks if you are using someone else's words, HOW MANY WORDS???

PLAGIARISM

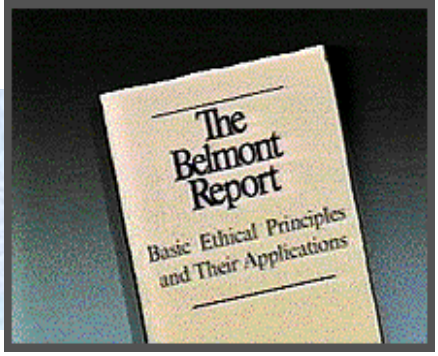
Continue……



✓At the beginning of a paraphrased section, show that what comes next is someone else's original idea (example: these bullet points start out by saying the information originated with Northwestern University),

✓At the end of a paraphrased section, place the proper citation. 15

Redundant Duplication



- Redundant publications constitute a special type of plagiarism.
- The **ICMJE** defines redundant publication as follows:

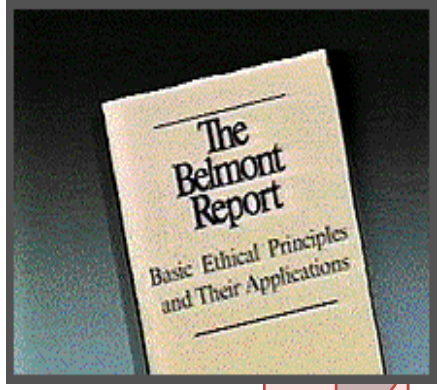
> **"Redundant or duplicate publication is publication of a paper that overlaps substantially with one already published."**

Remember

Articles that have been published already should not be either resubmitted under another title, or resubmitted with only minor changes to the text unless it is clearly stated that it is a resubmitted article

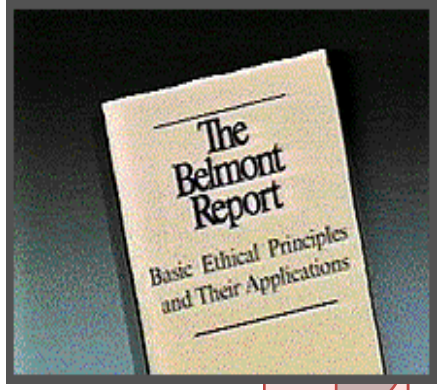
PLAGIARISM

Case Study



Belinda is publishing her first article that builds on the research of a similar project she did three years prior with her colleague, Isaiah. In Belinda's current article she has placed a graph from the article she and Isaiah co-authored about their previous research. Isaiah created the original graph. Does Belinda have to site the previous article?

PLAGIARISM



Answer……

Yes. Belinda is using the ideas of another person(s). Even though the graph came from an article she herself worked on, she should appropriately cite the prior publication to show that:

a) the data and results described in the graph are not new and have been previously published; and,

b) the idea originated with another article (in this instance the other article is the research team of Belinda and Isaiah).

PEER REVIEW

DEFINITION AND IMPORTANCE

Peer review is the process in which an author (or authors) submits a written manuscript or article to a journal for publication and the journal editor (peer review process) distributes the article to experts (reviewers) working in the same, or similar, scientific discipline.

PEER REVIEW

The peer review process involves the following:

1. Reviewers and editors read and evaluate the article

2. Reviewers submit their reviews back to the journal editor

3. The journal editor takes all comments, including their own, and communicates this feedback to the original author (or authors)

PEER REVIEW

According to an article on quality peer reviews in the *Journal of the American Medical Association*, **a high quality peer review should evaluate a biomedical article or publication on the**

- **Importance** – Does the research impact health and health care?
- **Usefulness** – Does the study provide useful scientific information?
- **Relevance** – Does the research apply to the journal's readers and content area of interest?

PEER REVIEW

Continue…..

Sound methods – Was the research conducted with sound scientific methods that allowed the researchers to answer their research question?

Sound ethics – Was the study conducted ethically ensuring proper protection for human subjects? Were results reported accurately and honestly?

PEER REVIEW

Continue…..

Completeness – Is all information relevant to the study included in the article?

Accuracy – Is the written product a true reflection of the conduct and results of the research? 20

PEER REVIEW

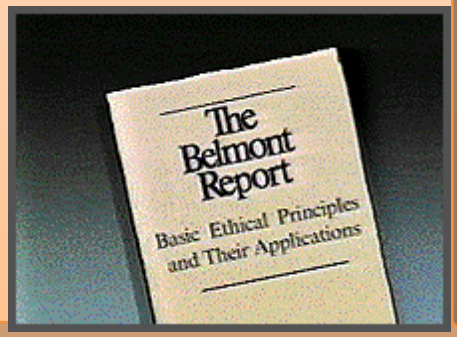
ETHICAL GUIDELINES

The two most important ethical concepts in the peer review process are;

- ❖confidentiality and
- ❖protection of intellectual property….In addition;
- ❖No conflicts of interest
- ❖No Political

21

(P16-17 read for info)



PEER REVIEW

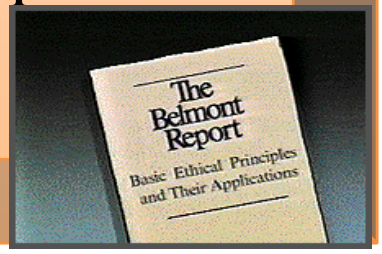
EXAMPLE CASE STUDY

Query Dr. Connelly is a faculty member at Springer University. He has been asked to review a publication for a biomedical journal. After receiving the article, he realizes the author is a student working under the guidance of a fellow faculty member in a neighboring department. The faculty member happened to mention the qualities of the student at a recent social gathering. Does Dr. Connelly have a reportable conflict of interest?

PEER REVIEW

Answer-----

The peer review process relies on a foundation of confidentiality. Dr. Connelly should contact the journal editor and report his belief that the manuscript originated from the university where he is employed. He and the editor should then open a dialogue about how this could potentially effect his participation in the peer review process and how to proceed.



DATA MANAGEMENT

DEFINITION AND IMPORTANCE

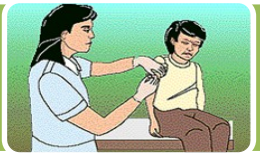
Data management, in respect to research ethics, indications three issues:

1) The ethical and truthful collection of reliable data;
2) The ownership and responsibility of collected data; and,
3) Retaining data and sharing access to collected data with colleagues and the public. [32,33]

DATA MANAGEMENT

Assigning and ensuring responsibility for collecting and maintaining data include the following important issues:

Oversight of the design of the method of data collection



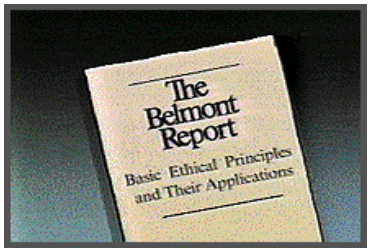
Protecting research subjects from harm

Responsible use of data and truthful interpretation of data results

Delegating work with data to others and responsibility over the work of others

Securing and storing data safely to preserve the integrity and privacy of data

DATA MANAGEMENT
Ethical Guidelines



- In order to address all the issues of data management in timely manner, researchers must consider the answer to the following questions:

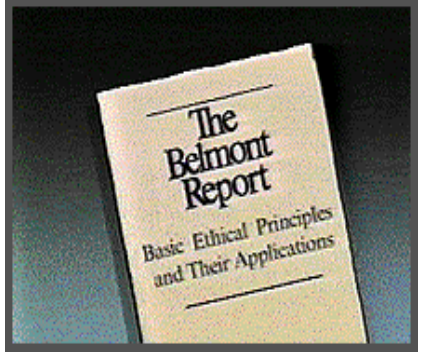
Who is in charge of the data? (usually the principal investigator of the project.)…….READ P.24

How will data be collected? (via phone, mail, personal interview, existing records, secondary sources, etc.?)

Will there be identifying information within the data? If yes, why? How will this be rectified?

DATA MANAGEMENT

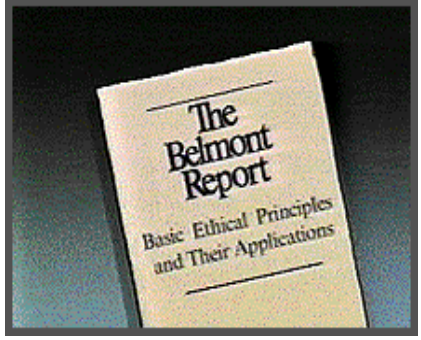
Continue……



- How will data be stored and what privacy and protection issues will result from the method of storage? (Will it be stored electronically, on paper, as raw tissue samples, etc.?)
- Who will ensure that no data were excluded from the final results and ensure accuracy of result interpretation?
- How long after the project is over will data be kept? (This will depend on the source of funding and organizational policies).

DATA MANAGEMENT

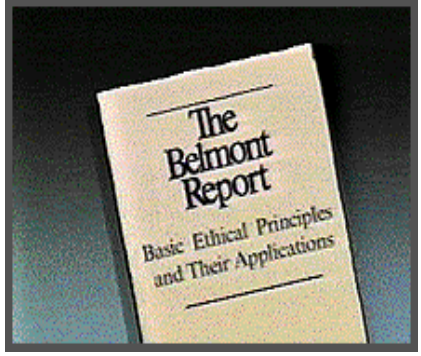
Continue……



Protecting **intellectual property** while at the same time encouraging data sharing is highly important in order to ensure valid and reliable research.

DATA MANAGEMENT

_Continue……



Intellectual property--- means P 24

Means any invention, discovery, improvement, copyrightable work, integrated circuit mask work, trademark, trade secret, and licensable know-how and related rights.

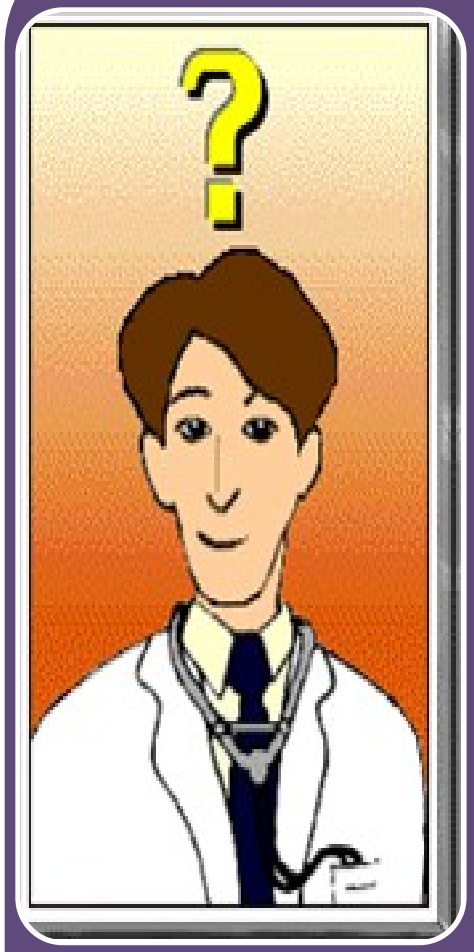
DATA MANAGEMENT

The **Health Information Portability and Accountability Act (HIPAA)** of 1996 provides detailed guidelines about data sharing and using data containing personal identification information.

The **HIPAA** guidelines protect personal health information and provide legal requirements for all segments of the health care system (including biomedical research) concerning what type of information can be shared, how information should be stored and protected, data coding, and how information is used.

DATA MANAGEMENT

EXAMPLE CASE STUDY



Joanne is a researcher at George Kent College. She collected data on rural mental health patients and just published an article on her research in a scholarly journal. Joanne plans to independently write a book about her research and develop educational tools that she can sell to professionals. Joanne is partly funded through her college, but most of her research was paid for with a private stipend from a charitable foundation. Joanne is reluctant to publicly disclose her data before her book is finished. Can she hold off on sharing her data until she completes her book?

DATA MANAGEMENT

Answer

Joanne has published an article on her data and according to NIH policies, she should be prepared to disclose her data at the time of publication. However, Joanne is not funded with NIH dollars. She would have to use her judgment about publishing her data and be prepared to give a strong reason to the editor of the journal (i.e. she is writing a book) as to why she isn't sharing her data at this time.

RESEARCH MISCONDUCT

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

RESEARCH MISCONDUCT

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
"The United States' Office of Scientific and Technology Policy (OSTP)"

Research misconduct can also be the result of mistaken, negligent, unintentional, lazy, or sloppy research practices.

In these instances of research misconduct, the use of outside research evaluators (like the IRB) and the process of peer review helps to maintain and safeguard scientific integrity.

RESEARCH MISCONDUCT

What should people do if they are suspected of having committed research misconduct

The Department of Health and Human Services Office of Research Integrity (DHHSORI) suggests the following procedural guidelines for reporting and investigating research misconduct;

1- A person suspecting a scientist of research misconduct should report the incident to a research integrity officer who should immediately look into the claim to assess if it is both:

a) research misconduct; and

b) within the control of the research institution.

RESEARCH MISCONDUCT

- 2- The person who informs the research integrity officer of suspected misconduct (the **whistleblower)** should be treated with “fairness and respect” by the research institution and efforts should be made to protect their job and reputation as necessary.

- 3. The person suspected of research misconduct (the **respondent)** should be protected and treated with “fairness and respect” by the research institution.

RESEARCH MISCONDUCT

- 4. The research integrity officer should strive to maintain the confidentiality of both the whistleblower and the respondent.

- 5. If the misconduct issue is a criminal one or exceeds the control of the research institution, the research integrity officer should report the misconduct claim to the proper authorities or agencies.

RESEARCH MISCONDUCT

EXAMPLE CASE STUDY

Marcus and Clay have been working on a research project studying the prevalence of pneumonia in nursing home residents. Marcus learns that while Clay is interviewing research participants, if he does not elicit an answer, he invents one and passes it off as truthful data collection. Marcus questions Clay and he denies the allegation.

What should Marcus do?

RESEARCH MISCONDUCT

Answer

Marcus is obligated to report Clay's activity to the person in charge of the research project. If this person does not respond and the behavior continues, Marcus should then go to his institution's officer research integrity. Marcus should not embellish any information or make assumptions, but merely report his observations. If Marcus is worried about his working relationship with Clay and the project's leadership, he should also report that concern to the research integrity office.

RESEARCH WITH HUMAN SUBJECTS

DEFINITION AND IMPORTANCE

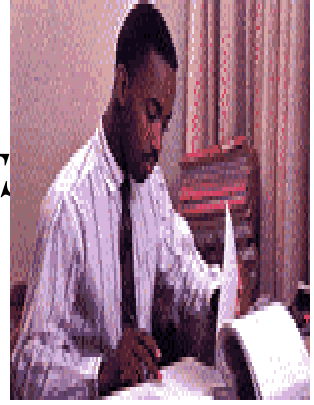
The issues concerning research with human subjects involves topics ranging from voluntary participation in research to fair selection and justice.

Informed consent means that people approached and asked to participate in a research study must:

a) know what they are getting involved with before they commit;
b) not be forced or manipulated in any way to participate; and,
c) must consent to participate in the project as a subject.

- Informed consent exists to ensure that all volunteered subjects understand what participation involve

RESEARCH WITH HUMAN SUBJECT



Requirements of informed consent

1)**The info disclosed to the participants must include**; "research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.

2)**Comprehension** – information has to be understandable to every participant, taking into consideration different abilities, intelligence levels, maturity, and language needs.

3) **voluntariness.** Informed consent can be neither persuaded nor improperly pressured from any participant

RESEARCH WITH HUMAN SUBJECTS

Respect for Persons

People have aright to protect themselves, and information gathered during research participation could harm a person by violating their right to keep information about themselves private.

The Health Information Portability and Accountability Act (HIPAA) has two main provisions:

1) prevents workers and their families from losing health insurance when changing jobs.
2) The Administrative Simplification Compliance Act (ASCA) contains strict regulations concerning health information privacy, security (particularly of electronically stored health data), and personal identifiers attached to data and maintained by health insurance companies, hospitals, clinics, researchers, and the government.

RESEARCH WITH HUMAN SUBJECTS

Respect for Persons

Risk benefit and beneficence :

Researchers must never subject research participants to more risk than necessary, be prepared to cease research if it is causing harm, and never put participants at a level of risk disproportionate to the anticipated benefits.

For example, research participants in an AIDS study could be asked to take an experimental drug to see if it alleviates their symptoms. The participants with AIDS take on a risk (ingesting the experimental drug) in order to benefit others (information on how well the drug works) at some time in the future.

RESEARCH WITH HUMAN SUBJECTS
ETHICAL GUIDELINES

Human subjects must voluntarily consent to research and be allowed to discontinue participation at any time.

Research involving human subjects must be valuable to society and provide a reasonably expected benefit proportionate to the burden requested of the research participant.

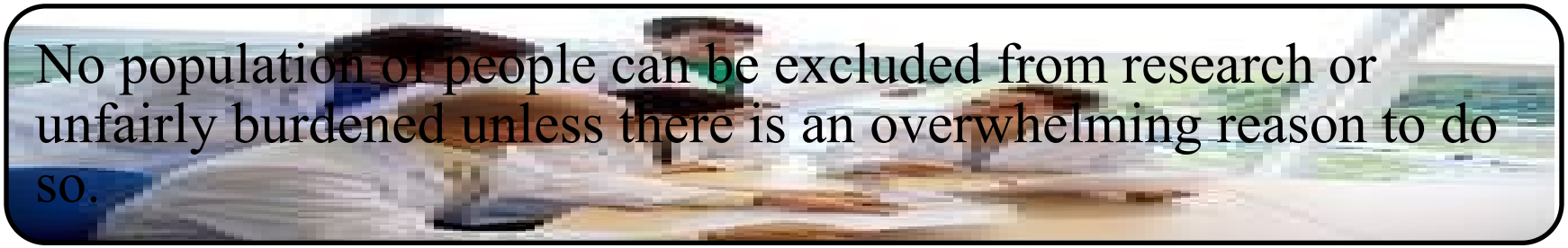
Research participants must be protected and safe. No research is more valuable than human well being and human life

RESEARCH WITH HUMAN SUBJECTS

Continue------

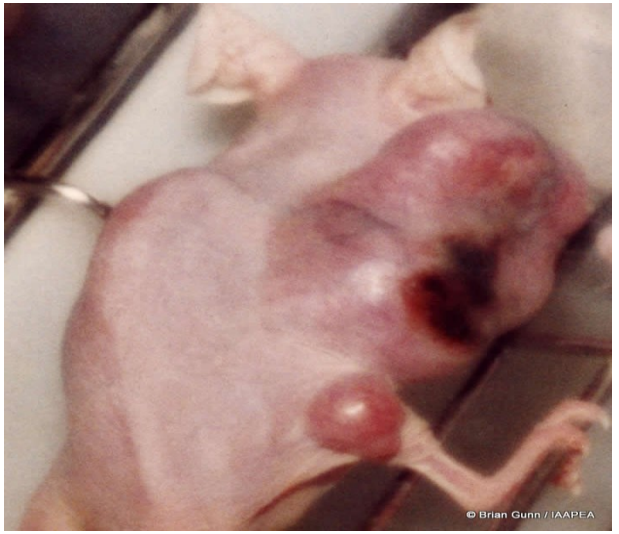
Researchers must avoid harm, injury, and death of research subjects and discontinue research that might cause harm, injury, or death.

Research must be conducted by responsible and qualified researchers.



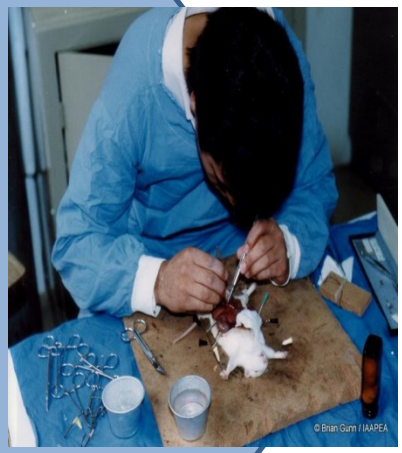
No population or people can be excluded from research or unfairly burdened unless there is an overwhelming reason to do so.

RESEARCH WITH ANIMALS



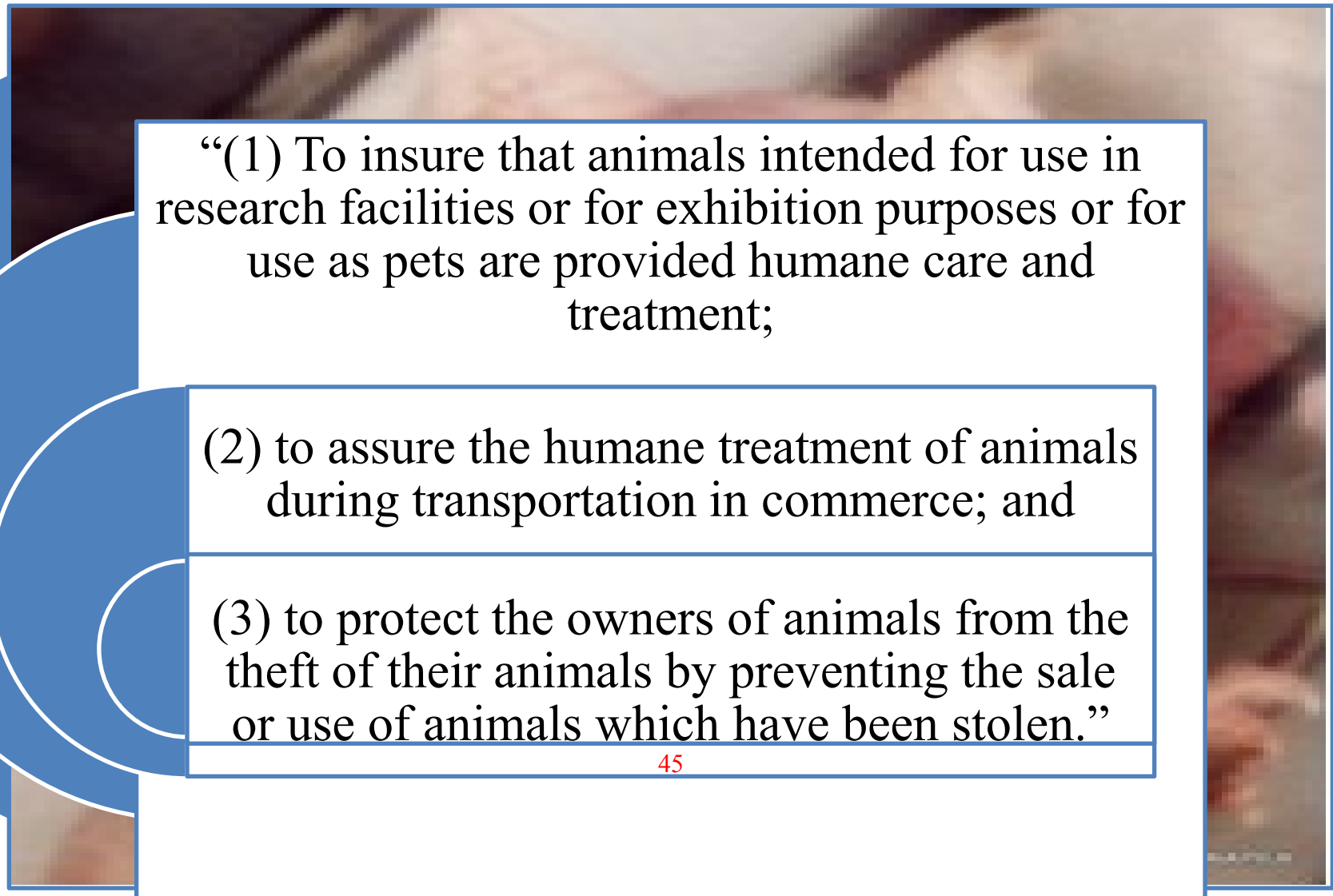
RESEARCH WITH ANIMALS

To assure that research with animals is conducted ethically and responsibly, the federal government has created regulations involving the use and care of animals involved in teaching, testing, and research.



RESEARCH WITH ANIMALS

The Animal Welfare Act in 1966 (last revised in 1990) exists in order:



"(1) To insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment;

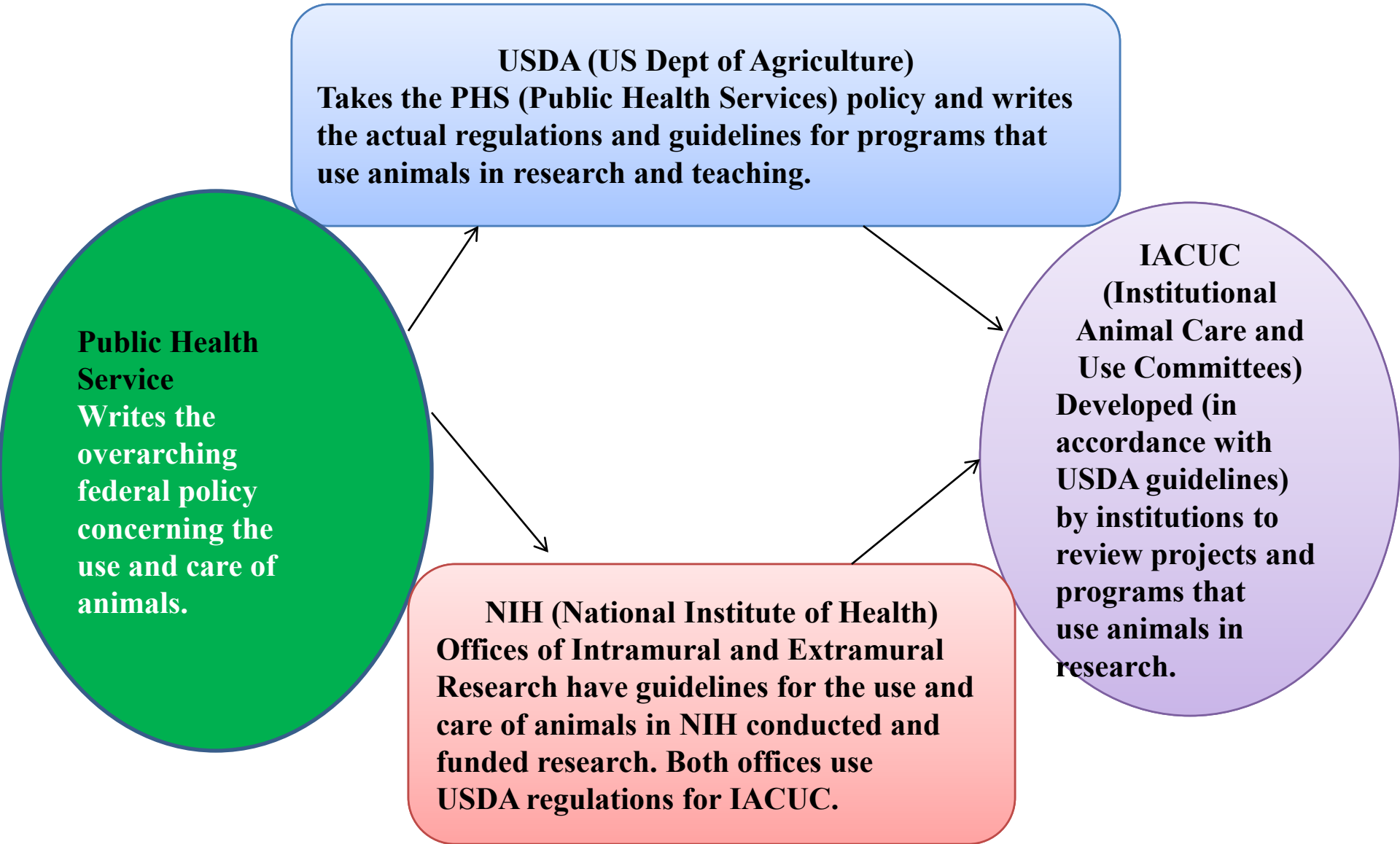
(2) to assure the humane treatment of animals during transportation in commerce; and

(3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen."

RESEARCH WITH ANIMALS

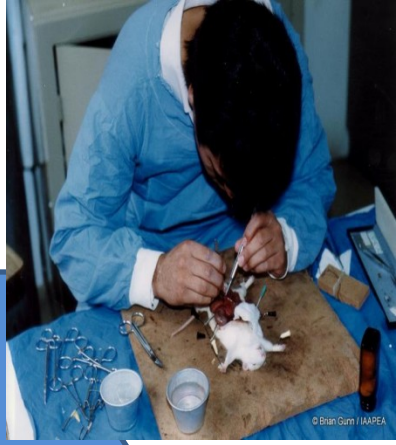
The responsibility for enforcing the Animal Welfare Act and protecting animals used in testing, teaching, and research falls on a variety of agencies responsible for different issues involving the use of animals are:

RESEARCH WITH ANIMALS



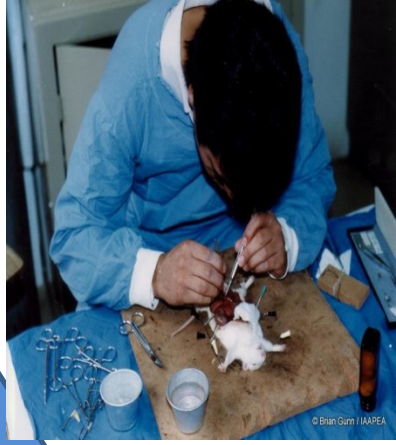
RESEARCH WITH ANIMALS

EXAMPLE CASE STUDY



Dr. Xiang conducts research studying antibacterial treatment for infected skin wounds. He wants to study the infection rate of a particular bacteria and see if it responds to a new antibiotic drug he has developed. In order to test the drug, Dr. Xiang must first inflict shallow wounds on animals, then infect the wounds with the bacteria, and finally apply the antibiotic drug to test its effectiveness. Dr. Xiang has two options:
a) inflict multiple wounds on a few animals; or, b) inflict fewer wounds on several animals. Which option is more attractive and the least harmful?

RESEARCH WITH ANIMALS
Answer



Is it better to minimize the number of animal subjects?
How much suffering can be born by one animal?
Can the data provide enough information for appropriate analyses?

- The IACUC at Dr. Xiang's institution must answer these questions to its satisfaction before approving the research proposal.

RESEARCH WITH HUMAN SUBJECTS

Institutional Review Board (IRB)

The way the federal government assures that research involving human subjects is conducted ethically is through the use of oversight by (IRBs) housed within research institutions across the country.

IRBs consist of a panel of biomedical research experts, ethicists, and members of the community who carefully discuss and weigh the risks research participants will undergo and compare this risk to potential benefits.

RESEARCH WITH HUMAN SUBJECTS

IRB MISSION

The mission of the IRB is to review research proposals in which there are human participants to ensure ethical research that;

- Balances potential risk to the participants with anticipated benefits
- Offers protection to participants from unnecessary harm
- Offers proportional compensation to participants

RESEARCH WITH HUMAN SUBJECTS

Continue……

The person in charge of the research is a qualified scientist

Informed consent and other forms are readable, understandable and ensure voluntary participation.

Taken from the NIH Office of Human Subjects Research website. http://206.102.88.10/ohsrsite/index

RESEARCH WITH HUMAN SUBJECTS

IRB at KSU

"The National Comity for Bioethics and Medical Ethics"--1422 H

- KSU Joined this comity and established:----

"The Local Comity for Research Ethics at KSU"

THANK YOU