Academic Paper Writing
Research Ethics

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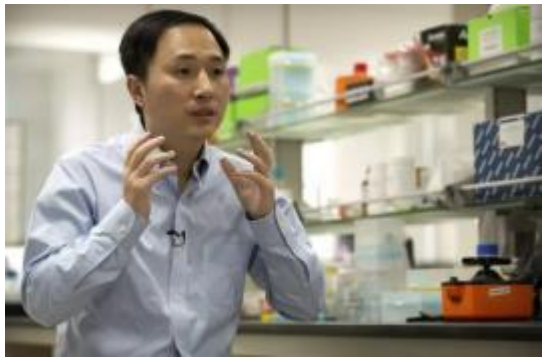
What do you think about this?



基因编辑婴儿事件

编辑 上传视频

2018年11月26日，南方科技大学副教授贺建奎宣布一对名为露露和娜娜的基因编辑婴儿于11月在中国健康诞生，由于这对双胞胎的一个基因（CCR5）经过修改，她们出生后即能天然抵抗艾滋病病毒HIV。这一消息迅速激起轩然大波，震动了世界。

2018年11月26日，国家卫健委回应"基因编辑婴儿"事件，依法依规处理。[1] 11月27日，科技部副部长徐南平表示，本次“基因编辑婴儿”如果确认已出生，属于被明令禁止的，将按照中国有关法律和条例进行处理；[2] 中国科协生命科学学会联合体发表声明，坚决反对有违科学精神和伦理道德的所谓科学研究与生物技术应用。[3] 11月28日，国家卫生健康委员会、科学技术部发布了关于“免疫艾滋病基因编辑婴儿”有关信息的回应：对违法违规行为坚决予以查处。[4]

2019年1月21日，从广东省“基因编辑婴儿事件”调查组获悉，现已初步查明，该事件系南方科技大学副教授贺建奎为追逐个人名利，自筹资金，蓄意逃避监管，私自组织有关人员，实施国家明令禁止的以生殖为目的的人类胚胎基因编辑活动。[5] 12月30日，“基因编辑婴儿”案在深圳市南山区人民法院一审公开宣判。贺建奎、张仁礼、覃金洲等3名被告人因共同非法实施以生殖为目的的人类胚胎基因编辑和生殖医疗活动，构成非法行医罪，分别被依法追究刑事责任。[6]

Should a vaccine be used without enough clinical trials?

COVID-19 Vaccination

Clinical Resources for Each COVID-19 Vaccine

Find information for COVID-19 vaccination administration, storage and handing, reporting, and patient education for each specific vaccine

Product Information by US Vaccine

Face Recognition? Can I use these faces over here?

It is all about RESEARCH ETHICS!

What is research ethics?

Ethics:
principles for guiding decision making and reconciling conflicting values.

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.

-- from “A Guide to Research Ethics” by University of Minnesota

Is research ethics a moral problem or a scientific problem?

People may disagree on ‘ethics’ because it is based on people's personal value systems. What one person considers to be good or right may be considered bad or wrong by another person.

Contents

Background – Brief History

- The birth of modern research ethics began with a **desire to protect human subjects** involved in research projects.
- The **first attempt** to craft regulations began during the Doctors Trial of 1946-1947. The Doctors Trial was a segment of the Nuremberg Trials for **Nazi** war criminals.
- In the Doctors Trial, 23 **German Nazi physicians** were accused of conducting abhorrent and torturous "experiments" with concentration camp inmates.
- The accused physicians **tortured, brutalized, crippled, and murdered** thousands of victims **in the name of research**.
- Some of their experiments involved gathering scientific information about the limits of the human body by exposing victims to extreme temperatures and altitudes. The most gruesome and destructive experiments tested how quickly a human could be euthanatized in order to carry out the Nazi racial purification policies most efficiently.

Photo of the Nuremberg Palace of Justice
Photo by: Thomas J. Dodd Papers, Dodd Research Center, University Libraries, University of Connecticut

Background – Nuremberg Code

- To prosecute the accused Nazi doctors for the atrocities they committed, a list of ethical guidelines for the conduct of research – the **Nuremberg Code** – were developed.

- Nuremberg Code – 10 guidelines:

1. Research participants must voluntarily **consent to research participation**
2. Research aims should contribute to **the good of society**
3. Research must be based on **sound theory and prior animal testing**
4. Research must **avoid** unnecessary physical and mental suffering
5. **No** research projects can go forward where serious injury and/or death are potential outcomes
6. The degree of risk taken with research participants **cannot** exceed anticipated benefits of results
7. Proper environment and **protection** for participants is necessary
8. Experiments can be conducted only by scientifically **qualified persons**
9. Human subjects must be allowed **to discontinue** their participation **at any time**
10. 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

Background – Helsinki Declaration

- The Helsinki Declaration was developed by the **World Medical Association** and has been revised and updated periodically since 1964, with **the last update occurring in 2000**.
- The document lays out basic **ethical principles** for conducting biomedical research and specifies guidelines for research conducted either by a physician, in conjunction with medical care, or within a clinical setting.
- The **Helsinki Declaration** contains all the basic ethical elements specified in the Nuremberg Code.
- Unique principles within Helsinki Declaration

1. The necessity of using an independent investigator to **review** potential research projects
2. Employing a medically qualified person to **supervise** the research and assume responsibility for the health and welfare of human subjects
3. The importance of **preserving the accuracy of research results**
4. **Suggestions** on how to obtain informed consent from research participants
5. Rules concerning research with **children** and **mentally incompetent persons**
6. **Evaluating and using experimental treatments on patients**
7. The **importance** of determining which medical situations and conditions are appropriate and safe for research

Background – Belmont Report

- Following the Helsinki Declaration, the next set of research ethics guidelines came out in the **Belmont Report of 1979** from the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- The **Nuremberg, Helsinki, and Belmont guidelines** provided the **foundation** of more ethically uniform research, to which stringent rules and consequences for violation were attached. Governmental laws and regulations concerning the responsible conduct of research have since been developed for research that involves **both human and animal subjects**.
- The **Animal Welfare Act** provides guidelines and regulations for research with animals. It goes into detail about sale, licensure, facilities, transport, and other care instructions.

Why Study Research Ethics?

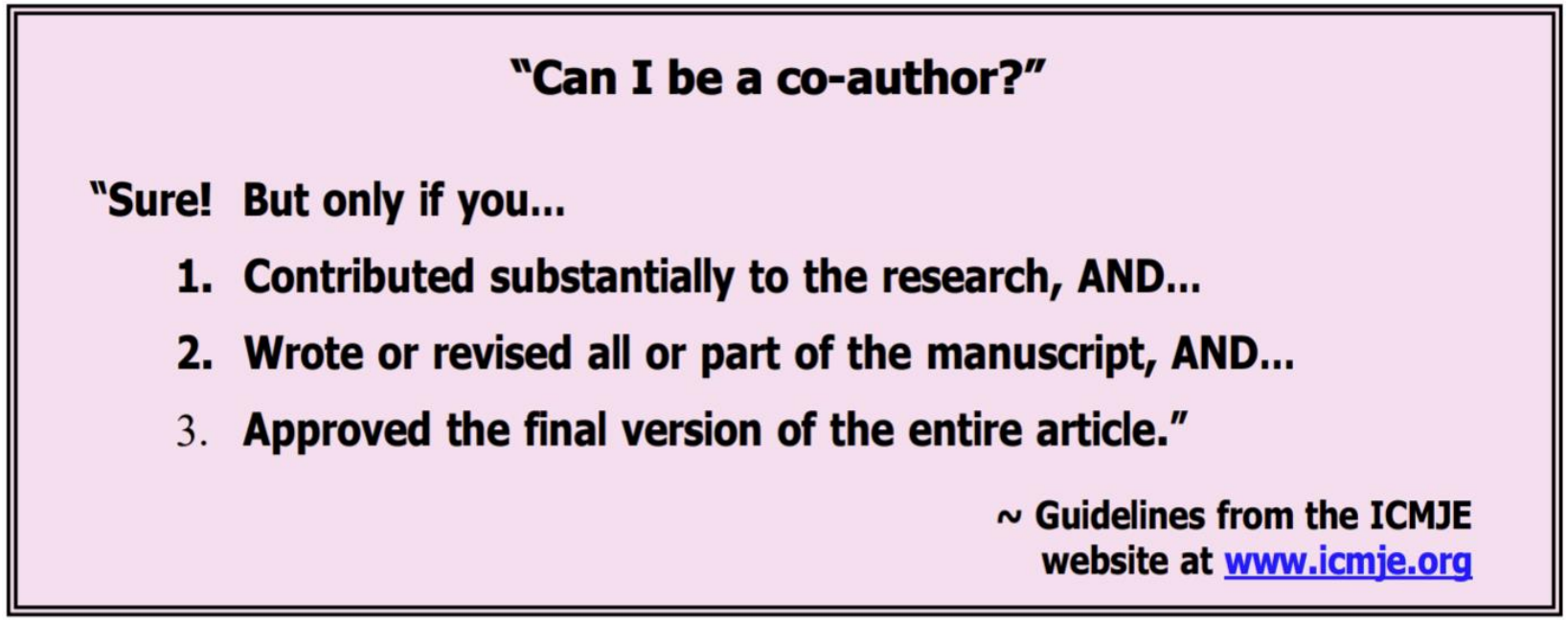
- Knowing what constitutes ethical research is **important** for all people who conduct research projects or use and apply the results from research findings.
- **All researchers** should be familiar with the basic ethical principles and have up-to-date knowledge about policies and procedures designed to ensure the safety of research subjects and to prevent sloppy or irresponsible research, 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 is a **public trust** that must be ethically conducted, trustworthy, and socially responsible if the results are to be valuable.
- All parts of a research project – from the project design to submission of the results for peer review – have to be **upstanding** in order to be considered ethical.
- When even one part of a research project is questionable or conducted unethically, the **integrity** of the entire project is called into question.

Authorship

- 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**.
- **Responsible** authorship practices are an important part of research.
- Despite its vital role, authorship remains a **murky and vague** area for many scientists who frequently run into difficulty when deciding which colleagues should be listed as authors or coauthors, and which colleagues should instead receive acknowledgement.
- Despite the challenges, researchers should familiarize themselves with proper **authorship practices** in order to protect their work and ideas while also preventing research fraud.

Authorship-Ethical Guidelines

- 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.



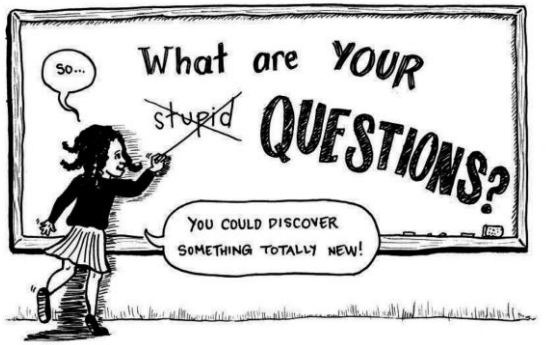
First Author *vs* Corresponding Author

Usual Practice:

- **First author** is usually the student /researcher who has undertaken the research work. First author is often also **referred as the presenting author**. He /She is responsible for doing the research practically along with the co-authors who might assist him/ her in the research work or might be the colleagues from the same work group. **He is also responsible for preparing the manuscript and analyzing the data**.
- **Corresponding author is usually the senior author** who provides the **intellectual input and designs and approves the protocols** to be followed in the study. **He is responsible for the manuscript correction, proof reading, whole correspondence during the paper submission**, **handling the revisions and re-submission of revised manuscripts up to the acceptance of the manuscripts.**

- How about co-first authors and co-corresponding author?
- How about second author and other authors?

Example Case Study



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. 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?

Plagiarism

- **Plagiarism is the act of passing off somebody else's ideas, thoughts, pictures, theories, words, or stories as your own.** If a researcher plagiarizes the work of others, they are bringing into question the **integrity**, **ethics**, and **trustworthiness** of the sum total of his or her research. In addition, plagiarism is both an **illegal act and punishable**, considered to be on the same level as **steal**ing from the author that which he or she originally created.
- Plagiarism takes many forms:

1) 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.
2) 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

No part of the spectrum of potential plagiaristic acts are **tolerated** by the scientific community, and research manuscripts will be **rejected** by publishers if they contain any form of plagiarism including **unintentional plagiarism**.

Plagiarism – Ethical Guidelines

The **Indiana University** provides the following advice to avoid plagiarism:

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;
- **Borrows** facts, statistics, or other illustrative material, **unless the information is common knowledge**."

The rules of plagiarism typically apply to **graphics, text, and other visuals from all traditional forms of publication** and include **modern forms** of publications as well, in particular the **World Wide Web**. If a substantial amount of another person's graphics or text will be lifted from a web page, an author should ask permission to use the material from the original author or website host

Plagiarism – Ethical Guidelines

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

- **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,
- 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**.

Plagiarism – Redundant Publication

The ICMJE defines redundant publication as follows:

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

The ICMJE further points out that:

Resubmitting a manuscript to a journal when it has already been published elsewhere violates, "**international copyright laws, ethical conduct, and cost-effective use of resources**."

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 – Example 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, Jackie. In Belinda's current article **she has placed a graph** from the article she and Jackie co-authored about their previous research. Jackie created the original graph. **Does Belinda have to site the previous article**?

Plagiarism – Example Case Study

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 depicted in the graph are not new and have been previously published;

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

Peer Review

- **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 distributes the article to experts working in the same, or similar, scientific discipline.**
- The experts, otherwise called the **reviewers**, and the editor then enter the peer review process.
- The **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)

The peer review process seldom proceeds in a straight line. The entire process may involve **several rounds** of communication between the editor, the reviewers, and the original author (or authors) before an article is fully ready for publication.

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 following **merits**:

- **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?
- **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?
- **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?

My Experience:

Clear Writing is the top one merit.

Peer Review – Ethic guidelines

1. The two most important ethical concepts in the peer review process are :

- Confidentiality
- Protection of intellectual property

2. Double blind Peer Review: Reviewers should not know the author (or authors) they are reviewing, and the author (or authors) should not be told the names of the reviewers.

Only by maintaining strict **confidentiality** guidelines can the peer review process be truly open and beneficial. Likewise, no person involved in the peer review process – either editor, reviewers, or other journal staff – can publicly disclose the information in the article or use the information in a submitted article for personal gain.

3. Peer reviewers can be **neither conflicted nor political** in their review.

- **Conflicts** may take the form of financial conflicts with the results, conflicts if the research is too similar to their own research endeavors, and conflicts due to personal relationships with the author (or authors).
- **Political** motivations that might interfere with the peer review process include competition to publish with other scientists and inaccurate reviews designed to “punish” a competing colleague or journal

Conflicts on Interests

- **Conflicts of interest arise when a person's (or an organization's) obligations to a particular research project conflict with their personal interests or obligations.**

For example, a university researcher who owns stock in XYZ Pharmaceuticals is obligated to report truthful and accurate data, but he might be conflicted if faced with data that would hurt stock prices for XYZ pharmaceuticals.

- **Conflicts of interest are particularly important to examine within the context of biomedical research because research subjects may be particularly vulnerable to harm**.

It is imperative to address conflicts of interest up front and discuss how to combat potential lack of objectivity, before the research is called into question

Conflicts on Interests – Ethic Guidelines

The “Objectivity in Research NIH Guide,” provides guidelines on how investigators receiving grants from the National Institutes of Health (NIH) should handle conflicts of interest.

In essence, it suggests that investigators should:

- Disclose to their institution any major or significant financial conflicts of interest that might interfere with their ability to conduct a research project objectively
- Disclose any such financial conflicts of interest of their spouses or dependent children

Conflicts on Interests – Ethic Guidelines

NIH regulations for organizations receiving NIH funding:

- The **organization must have**, "**a written and enforced administrative process** to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought;"
- Before any NIH funds are spent, the organization must inform the Chief Grants Management Officer (CGMO) at the appropriate NIH office of **any existing conflicts** of interest and indicate that the conflict has been addressed, "by indicating whether the conflict has either been managed, reduced, or eliminated;"
- **The organization** has to **identify and report any conflicts** that arise during the course of NIH funded research;
- **The organization has to comply** with NIH requests for information on how an identified conflict of interest has been handled.

Conflicts on Interests – Case Study

Query Dr. Garrath is a gynecological physician and an investigator on a research project for a pharmaceutical company testing a new topical treatment for a sexually transmitted disease that must be administered frequently and can cause itching and irritation. The company is paying her a rate of $2,000 per person enrolled. Does she have a conflict of interest?

Answer Yes. Dr. Garrath's obligation to her patients has the potential to be compromised by her personal interests. While her job is to protect and promote her patients' welfare and health, at $2,000 per person enrolled, she might be tempted to recruit more people into the study for her personal financial benefit by encouraging her patients to participate and downplaying the side-effects and burdens of participation.

Data Management

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

1) the ethical and truthful **collection** of reliable data;
2) the **ownership** and **responsibility** of collected data;
3) **retaining** data and **sharing** access to collected data with colleagues and the public.

A clear, responsible, ethically sound, and carefully outlined **plan** for data management is required at the beginning of research to **prevent** all **manners of conflicts** and **inappropriate research methods**.

Data Management

- **Ethical data collection** refers to collecting data in a way that does not harm or injure someone. Harm and injury could range from outright physical injury to harmful disclosure of unprotected confidential health information.
- **Truthful data collection** refers to data that, once collected, are not manipulated or altered in any way that might impact or falsely influence results.
- **Truthful and ethical data collection and maintaining data** means:

1) **Oversight** of the design of the method of data collection
2) **Protecting** research subjects from harm
3) **Securing and storing** data safely to preserve the **integrity and privacy of data**
4) **Delegating** work with data to others and responsibility over the work of others
5) **Responsible** use of data and **truthful** portrayal of data results

Regarding Data Sharing

- Data sharing, though complicated by personal emotions, motives, obligations, and ownership, is considered to be a hallmark of the scientific community, particularly in academia.
- NIH describes **the importance of data sharing** on its website:
    1) Data sharing achieves many important goals for the scientific community, such as **reinforcing open scientific inquiry**, **encouraging diversity of analysis and opinion**, **promoting new research**, **testing of new or alternative hypotheses and methods of analysis**, **supporting studies on data collection methods and measurement**, **facilitating teaching of new researchers**, **enabling the exploration of topics not envisioned by the initial investigators**, and **permitting the creation of new data sets by combining data from multiple sources**.
    2) Data Sharing concerns with **intellectual property**.

Data Management-Ethical Guidelines

- The University of Minnesota's Intellectual Property Policy defines **intellectual property** as:

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

- In February of 2003, **NIH** released guidelines on data sharing. The primary guideline states that **all data must be shared and released in a timely manner**. The NIH defines **timely manner as "no later than acceptance for publication."**

Data Management-Case Study

- **Query 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 26 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?
- **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 （学术不端）

- The United States' Office of Scientific and Technology Policy (OSTP) defines research misconduct and its components, as follows:

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

1) **Fabrication** is making up data or results and recording or reporting them.
2) **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.
3) **Plagiarism*** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
4) Research misconduct **does not** include honest error or differences of opinion.

Research Misconduct （学术不端）

- OSTP presents guidelines on what must be present in order to find a researcher guilty of committing research misconduct:

A finding of research misconduct requires that:

1) There be a significant departure from accepted practices of the relevant research community.
2) The misconduct be committed intentionally, or knowingly, or recklessly.
3) The allegation be proven by a preponderance of evidence.

Making up research data that doesn't exist and other overt acts of fraud are deliberate and punishable criminal acts！！！！！！！！

Research Misconduct （学术不端）

- **What should people do if they are suspected of having committed research misconduct**?
- The US Department of Health and Human Services Office of Research Integrity suggests:

1) A person suspecting a scientist of research misconduct should **report** the incident to a research integrity officer who should immediately look into the allegation to assess if it is both: a) research misconduct; and b) within the jurisdiction of the research institution.

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.

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 jurisdiction of the research institution, the research integrity officer should **report** the misconduct allegations to the proper authorities or agencies.

The above procedure is not mandatory, but adopted by nearly all research institutions worldwide.

Research with Animals

- Animals play a significant role in research. They are used in a variety of ways by researchers, such as for **testing new pharmaceuticals**, as **teaching tools** for medical students, and as **experimental subjects** for new surgical procedures.
- Some organizations are interested in eliminating the use of animals in research. Others consider research with animals a necessary evil to the advancement of medicine, but still aim to eliminate unnecessary suffering, pain, and poor facility conditions for animal subjects.
- **To protect animals, research projects that use animals have to be reviewed**, like judging how much pain is too much.

Research with Human Subjects

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

- **Respect for Persons – Informed Consent.**
- Informed consent exists to ensure that **all research involving human subjects allows for voluntary participation by subjects who understand what participation entails**. 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 coerced or manipulated in any way to participate; and, **c)** must consent to participate in the project as a subject.

Research with Human Subjects

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

- **Respect for Persons – Privacy and confidentiality.**
- Privacy and confidentiality are very important components for research involving human subjects**. People have a right to protect themselves, and information gathered** during research participation could harm a person by violating their right to keep information about themselves private. The information gathered from people in biomedical studies has a unique potential to be particularly embarrassing, harmful, or damaging.

Research with Human Subjects

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

- **Risk benefit and beneficence**.
- Beneficence is a principle used frequently in research ethics. It means, "**doing good**." Biomedical research strives to do good by studying diseases and health data to uncover information that may be used to help others.
- The crux of this issue lies in the fact that uncovering information that may one day help people must be gathered from people who are living and suffering today. **While research findings may one day help do good, they may also cause harm to today's research participants**.

Research with Human Subjects

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

- **Justice**.
- Particular interest has been paid lately to preventing the overburdening of some populations in order to apply research findings to other groups. Populations under consideration with particular potential for exploitation may include the following:

Minority Groups, Women, Mentally Impaired Individuals, Children, Financially Disadvantage Individuals, Disadvantage People Living in Third World Countries, Prisoners, the Deceased, and Employees.

Research with Human Subjects - Guidelines

Guidelines for the use of human subjects in research are relatively recent, with the first modern and formal efforts to protect human subjects coming after World War II.

1) Human subjects must **voluntarily consent** to research and be allowed to discontinue participation at any time.
2) Research involving human subjects must be **valuable** to society and provide a reasonably expected benefit proportionate to the burden requested of the research participant.
3) Research participants must be **protected and safe**. No research is more valuable than human well being and human life.
4) Researchers must **avoid** harm, injury, and death of research subjects and discontinue research that might cause harm, injury, or death.
5) Research must **be conducted by** responsible and qualified researchers.
6) **No population of people can be excluded** from research or unfairly burdened unless there is an overwhelming reason to do so.