

**A GUIDE TO
RESEARCH
ETHICS**

**UNIVERSITY OF MINNESOTA
CENTER FOR BIOETHICS
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RESEARCH ETHICS: BACKGROUND AND DEFINITION

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.

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 (see photo^{*}). 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

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.

* Thomas J. Dodd Papers website. <http://www.lib.uconn.edu/DoddCenter/ASC/dodphot1.htm>. Accessed 2/05/03.

The Nuremberg Code consisted of ten basic ethical principles that the accused violated.¹
The 10 guidelines were as follows:

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



The Nuremberg Guidelines paved the way for the next major initiative designed to promote responsible research with human subjects, the **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 2000.² 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 but then advances further guidelines specifically designed to address

the unique vulnerabilities of human subjects solicited to participate in clinical research projects. The unique principles developed within the Helsinki Declaration include:

- 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
- The importance of preserving the accuracy of research results
- Suggestions on how to obtain informed consent from research participants
- 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

Following the Helsinki Declaration, the next set of research ethics guidelines came out in the **Belmont Report** of 1979 from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report outlines:

1. The ethical principles for research with human subjects
2. Boundaries between medical practice and research
3. The concepts of respect for persons, beneficence, and justice
4. Applications of these principles in informed consent (respect for persons), assessing risks and benefits (beneficence), and subject selection (justice)³



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. For research with human subjects **Title 45, Part 46 from the Code of Federal Regulations (45 CFR 46): The Protection of Human Subjects Regulations** outlines the purpose and policies of **Institutional Review Board (IRB)** oversight and approval, informed consent, and protections and policies for research with children, pregnant women, fetuses, prisoners, and mentally incompetent individuals.

Currently, the focus of research ethics lies in the education of researchers regarding the ethical principles behind regulations as well as the oversight and review of current and potential research projects. The field has expanded from providing protections for human subjects to including ethical guidelines that encompass all parts of research from research design to the truthful reporting of results.

There are several avenues for people who wish to seek education on basic ethical principles, and avenues for education on how to comply with policies at the institutional, state, and national levels. The University of Minnesota's Center for Bioethics (www.bioethics.umn.edu) and many other universities and professional associations around the country continually offer education for researchers and scientists on ethical research issues. Curriculum is available in frequently offered conferences, classroom settings, and on-line (www.research.umn.edu/curriculum).

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

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.⁴



Responsible authorship practices are an important part of research. Reporting and analyzing results is the key to applying research findings to the real world. 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 co-authors, 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.

ETHICAL GUIDELINES

Each person listed as an author on an article should have significantly contributed to both the research and writing. In addition, all listed authors must be prepared to accept full responsibility for the content of the research article. 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 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. 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.⁵

According to the ICMJE, colleagues who are part of a research group or team but do not meet the conditions above should NOT be listed as authors. They should instead receive acknowledgement at the end of the manuscript, with a brief description of their contribution if appropriate. In order to acknowledge a contributing colleague, the colleague must consent to the acknowledgement, lest they seem to be endorsing research or conclusions drawn from research for which they are not responsible.⁶

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.⁷ 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.

“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

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. 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?

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.

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES⁸

- University of Minnesota Code of Conduct for researchers (Section 2, Subdivisions 4 and 5) available online at:
<http://www1.umn.edu/regents/policies/academic/Conduct.html>
- University of Minnesota Publication of Investigation Results:
<http://www1.umn.edu/regents/policies/administrative/PublicationofResults.html>
- On-line curriculum on authorship issues by Mark Dworkin available at:
www.research.umn.edu/ethics. Click on "curriculum," then "authorship".

OTHER RESOURCES AND GUIDELINES

- The International Committee of Medical Journal Editors has a variety of helpful hints on a range of research ethics topics, including authorship. www.icmje.org.
- The following article suggests how to organize authorship when research is conducted in more than one institution.
Barker A. Powell RA. Authorship. Guidelines exist on ownership of data and authorship in multicentre collaborations. *British Medical Journal*, 1997; 314(7086):1046.

PLAGIARISM

DEFINITION AND IMPORTANCE

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.⁹ In addition, 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 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} 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.

ETHICAL GUIDELINES

The Indiana University website 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; or
- Borrows facts, statistics, or other illustrative material, unless the information is common knowledge."¹²

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.¹³

Most researchers certainly try not to plagiarize. However, it isn't always easy because people often consult a variety of sources of information for their research and end up mixing it in with their own background knowledge.¹⁴ 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.¹⁵

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."¹⁶

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.¹⁷

EXAMPLE CASE STUDY

Query 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?

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 depicted in the graph are not new and have been previously published; and, b) the idea originated with another entity (in this instance the other entity is the research team of Belinda and Isaiah).

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES¹⁸

- The University of Minnesota does not condone plagiarism. Plagiarism violates university policy and is not tolerated. For guidelines and Code of Conduct information, try the University of Minnesota's Office of Vice President of Research's website at www.research.umn.edu.

OTHER RESOURCES AND GUIDELINES

- The website www.plagiarism.org has been recommended by some researchers as a way to improve the quality of peer reviewed research publications. The website has a database of publications and can be used to detect plagiarism in a submitted manuscript.¹⁹
- The International Committee of Medical Journal Editors' website at www.icmje.org has resources on plagiarism and other ethical research issues, including how to reference all types of literature.

- Proper citation and referencing procedures can be obtained from the Modern Language Association's guidebook, *MLA Style Manual and Guide to Scholarly Publishing*. (2nd Edition) Joseph Gibaldi, ed., 1998. This guidebook is for graduate students, academicians, and professionals.
- For undergraduate students, proper citation guidelines are outlined in the *MLA Handbook for Writers of Research Papers*. (5th Edition) Joseph Gibaldi, ed., 1999.
- A reference article concerning plagiarism:
Price AR. Federal Actions against Plagiarism in Research. *Journal of Information Ethics*, 1996; 5(1):34-51.
- Another article about plagiarism and the Internet:
Eysenbach G. Report of a case of cyberplagiarism--and reflections on detecting and preventing academic misconduct using the Internet. *Journal of Medical Internet Research*, 2000; 2(1):E4.

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 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.

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?²⁰

ETHICAL GUIDELINES

The two most important ethical concepts in the peer review process are confidentiality and protection of intellectual property. 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 the 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.

Peer reviewers, in addition to maintaining confidentiality, 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.²¹

Editors may find it difficult to guarantee a conflict-free peer review process, because reviewers must be experts with knowledge unique to the field to which the article pertains. Therefore, many reviewers may find themselves faced with an article concerning research that is very similar to their own. Peer reviewers should disclose all conflicts of interest that may unduly influence their review to the journal editor and disqualify themselves when appropriate.

Editors of journals should maintain an open and ethical peer review process, and all submitting authors and readers should be fully aware of a journal’s process of peer

review. Editors do retain flexibility in assigning the number of peer reviewers and what to do with the peer review information once completed. One method is for an editor to approach two or three reviewers and then ask an author (or authors) to change the article to satisfy all the reviews. On the other hand, an editor may take all the reviews and consolidate the advice to help guide the author (or authors) when making changes, clarifications, and corrections.

Editors must not relinquish too many of their own responsibilities to peer reviewers. The peer review process represents one step in the publishing process and editors need to take full responsibility for their decision to include an article in their journal. This means that editors must review the content and character of a submitted article, using all the criteria listed for reviewers above, and should rely on the reviewers primarily to catch errors that lie outside the editor's area of expertise and technical understanding.²²

Finally, editors should have full and complete freedom over the content of a published journal. They should only include articles that they believe to be honest, accurate, ethical, and scientifically responsible. According to the International Committee of Medical Journal Editors, all editors have:

"An obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical community."²³

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 merits of the student at a recent social gathering. Does Dr. Connelly have a reportable conflict of interest?

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.

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES²⁴

- The University of Minnesota's Board of Regents' guidelines regarding intellectual property can be found on-line at:
<http://www1.umn.edu/regents/policies/academic/IntellectualProperty.pdf>

OTHER RESOURCES AND GUIDELINES

- The International Committee of Medical Journal Editors website at www.icmje.org has information on the peer review process.

CONFLICTS OF INTEREST

DEFINITION AND IMPORTANCE

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.²⁵

A researcher should attempt to identify potential conflicts of interest in order to confront those issues before they have a chance to do harm or damage. If conflicts of interest do exist, then the objectivity of the researcher and the integrity of the research results can be questioned by any person throughout the research review process – from the IRB review through the peer review phase. It is therefore imperative to address conflicts of interest up front and discuss how to combat potential lack of objectivity, before the research is called into question.²⁶

ETHICAL 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:²⁷

- 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

The Title 42 Code of Regulations (42 CFR 50) section on conflicts of interest contains the *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought* guidelines, which consist of the following 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.²⁸

The NIH recommends the following possible actions to help organizations address conflicts of interest:

- “Public disclosure of significant financial interests;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded by PHS;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or potential conflicts.”²⁹

Physician and other health care professional researchers may find themselves facing conflicts of interest in their duties towards research versus their duties towards the health and welfare of their patients. Clinical obligations to patients should always be considered above and beyond the obligations of research.

EXAMPLE 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.

Dr. Garrath should very carefully evaluate whether this conflict of interest might impact her patients' health and welfare and how to solve this potential conflict before agreeing to be an investigator. She should also report this potential conflict to the proper administration authority at the clinical site where she is practicing.³⁰

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES³¹

- The University of Minnesota's policies on reporting conflicts of interest can be found at: <http://www1.umn.edu/regents/policies/academic/ConflictofInterest.pdf>.

OTHER RESOURCES AND GUIDELINES

- The Association of American Universities' (AAU) *Report on Individual and Institutional Financial Conflict of Interests* provides recommendations and guidelines for members on handling financial conflicts of interest: <http://www.aau.edu/research/COI.01.pdf>.
- Federal regulations can be found in the *Public Health Service Regulation: Responsibility of Applicants for Promoting Objectivity in Research*. Available on-line at: <http://grants.nih.gov/grants/guide/notice-files/not95-179.html>.

DATA MANAGEMENT

DEFINITION AND IMPORTANCE

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; and, 3) retaining data and sharing access to collected data with colleagues and the public.^{32,33} Each issue contributes to the integrity of research and can be easily overlooked by researchers. Oftentimes, researchers will downplay the importance of data management because the details can be time consuming and they assume they can “figure it out” as they go along. It is not adequate research practice to assume issues involved in data collection will work themselves out on their own. Instead, 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.

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. In comparison, truthful data collection refers to data that, once collected, are not manipulated or altered in any way that might impact or falsely influence results.

Assigning and ensuring responsibility for collecting and maintaining data is one of the most important ethical considerations when conducting a research project. Responsibilities include the following important issues:

- Oversight of the design of the method of data collection
- Protecting research subjects from harm
- Securing and storing data safely to preserve the integrity and privacy of data
- Delegating work with data to others and responsibility over the work of others
- Responsible use of data and truthful portrayal of data results

In contrast to the fairly straightforward concepts underlying truthful and ethical data collection issues, the issue of data sharing is complicated by personal emotions, motives, obligations, and ownership. Despite its complexities, data sharing is considered to be a hallmark of the scientific community, particularly in academia. NIH describes the importance of data sharing on its website:

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.³⁴

While part of scientific research encourages accuracy and verification of data through data sharing, sometimes data are associated with intellectual property and need to be protected as such. For this reason, whether to retain or share data can be a fine line for researchers who wish to protect their intellectual property, but the line must be properly drawn in order to allow the positive aspects of data sharing to occur while protecting the researcher's hard work and ingenuity.

ETHICAL GUIDELINES

The three issues for data management (ethical and truthful data collection, responsibility of collected data, and data sharing) can be addressed by researchers before and during the establishment of a new research project. Researchers must accurately identify answers to the following questions to resolve and address all data management issues in a timely manner:

- Who is in charge of the data? (This person is usually the principal investigator of the research project and is responsible for data collection design and physical data collection.)
- How will data be collected? (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?
- 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.)

Protecting intellectual property while at the same time encouraging data sharing is highly important in order to ensure valid and reliable research. In order to identify what is and is not protected as “intellectual property,” the concept must be clearly defined. 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. Intellectual property includes, but is not limited to, individual or multimedia works of art or music, *records of confidential information generated or maintained by the University*, *data*, texts, instructional materials, tests, bibliographies, *research findings*, organisms, cells, viruses, *DNA sequences*, *other biological materials*, probes, crystallographic coordinates, plant lines, chemical compounds, and *theses*.^{*} Intellectual property may exist in a written or electronic form, may be raw or derived, and may be in the form

^{*} Emphasis added.

of text, multimedia, computer programs, spreadsheets, formatted fields in records or forms within files, databases, graphics, digital images, video and audio recordings, live video or audio broadcasts, performances, two or three-dimensional works of art, musical compositions, executions of processes, film, film strips, slides, charts, transparencies, other visual/aural aids or CD-ROMS.³⁵

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.” In addition, all grant applications to the NIH for grants of at least \$500,000 are required to establish a data sharing plan or give an explanation as to why data will not be shared in the proposal (i.e. IRB allowance or institutional restrictions).³⁶

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.

Genetic information is an area of particular concern when considering the issues surrounding data management. Due to the wealth of information locked inside the human genome and the potential for using this information to determine a variety of conditions and genetic tendencies, including the potential to identify a person based on his or her genetic information, particular interest has been expressed in protecting the information found in DNA. Careful attention should be paid by researchers when using genetic information due to its sensitive nature.

EXAMPLE 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

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.

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES³⁷

- The University of Minnesota Intellectual Property Policy:
<http://www1.umn.edu/usenate/policies/intelproperty.html>.
- The University of Minnesota Code of Conduct:
<http://www1.umn.edu/regents/policies/academic/Conduct.pdf>.
- University of Minnesota Privacy and Security Project:
http://www.ahc.umn.edu/ahc_content/about/privacy/

OTHER RESOURCES AND GUIDELINES

- NIH Data Sharing website is: http://grants.nih.gov/grants/policy/data_sharing/.
- For Frequently Asked Questions about data sharing:
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.
- U.S. Department of Health and Human Services Office for Civil Rights HIPAA final regulations: <http://www.hhs.gov/ocr/hipaa/finalreg.html>

RESEARCH MISCONDUCT

DEFINITION AND IMPORTANCE

Research misconduct is the process of identifying and reporting unethical or unsound research. The United States' Office of Scientific and Technology Policy (OSTP) released a new definition of research misconduct that went into effect in December of 2000. OSTP defines 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.

- **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.
- **Plagiarism*** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.³⁸

In addition to defining research misconduct, the federal policy released by OSTP includes guidelines on what must be present in order to find a researcher guilty of committing research misconduct.

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and

* Emphasis (bolded text) added.

- The misconduct be committed intentionally, or knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.³⁹

Research misconduct can be the result of criminal behavior. For example, making up research data that doesn't exist and other overt acts of fraud are deliberate and punishable criminal acts. Government regulations and criminal punishments are necessary to prevent these criminal practices.

Research misconduct can also be the result of mistaken, negligent, unintentional, lazy, or sloppy research practices. These types of misconduct are usually covered by institutional policies and are punishable at the institutional level. 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.⁴⁰

ETHICAL GUIDELINES

Who is responsible for reviewing instances of research misconduct? Any person who knows that research is being conducted unethically should raise his or her concerns to the appropriate authorities, whether that person is involved in the research or not. The first step in this instance may likely be a confidential conversation with the person in charge of research integrity at an institution. Once research misconduct has been identified, all parties involved in the research must take responsibility to resolve the situation, including: the principal investigator, co-investigators, the institution hosting the research, the funding agency, and publishing journal editors, if applicable. While the federal government takes responsibility for research projects funded with federal money, it assigns the primary responsibilities of identifying and investigating research misconduct to the agency or institution hosting the research.

When someone is suspected of committing research misconduct, the proper procedure is to first launch an inquiry. If the inquiry reveals a potential research misconduct situation, the second step is to then conduct a full-scale investigation. Finally, the institution uses the information collected during the full-scale investigation to

make decisions concerning the presence of misconduct and its severity, and what appropriate corrective action should be taken, if needed.⁴¹

What should people do if they are suspected of having committed research misconduct? The Department of Health and Human Services Office of Research Integrity suggests the following procedural guidelines for reporting and investigating research misconduct. While the procedures are not mandatory, nearly all research institutions have adopted very similar procedures to the following:

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.⁴²

EXAMPLE CASE STUDY

Query 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?

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.

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES⁴³

- To anonymously report misconduct at the University of Minnesota, call 612-626-0227.
- The following website contains the process and procedure for dealing with research misconduct at the University of Minnesota:
http://www.fpd.finop.umn.edu/groups/ppd/documents/policy/reporting_violations.cfm#400

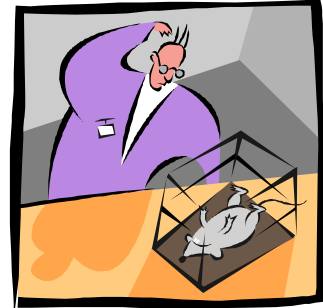
OTHER RESOURCES AND GUIDELINES

- United States Office of Research Integrity website: www.ori.dhhs.gov.
- Office of Science and Technology Policy website: www.ostp.gov.

RESEARCH WITH ANIMALS

DEFINITION AND IMPORTANCE

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. Research with animals is necessary and vital to biomedical research because animal research is frequently a necessary first step towards research involving new medical treatments and pharmaceuticals intended for human use.⁴⁴



Many dedicated organizations and individuals are interested in protecting and safeguarding animal subjects as regards their use in research. 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. These review processes assess the risks and benefits of using animals in research. This can prove difficult for project reviewers and often makes for intense debates and arguments about the appropriate use of animal subjects, particularly because the animal subjects usually bear all the risks while human beings realize all the benefits. Debates also center on judging how much pain is too much, whether or not animals experience pain in the same way that humans do, and whether or not these ideas should even factor into the debate at all.

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.

ETHICAL GUIDELINES

In order to prevent the mistreatment of animals the United States government first passed the Animal Welfare Act in 1966 (last revised in 1990). The Animal Welfare Act exists in order:

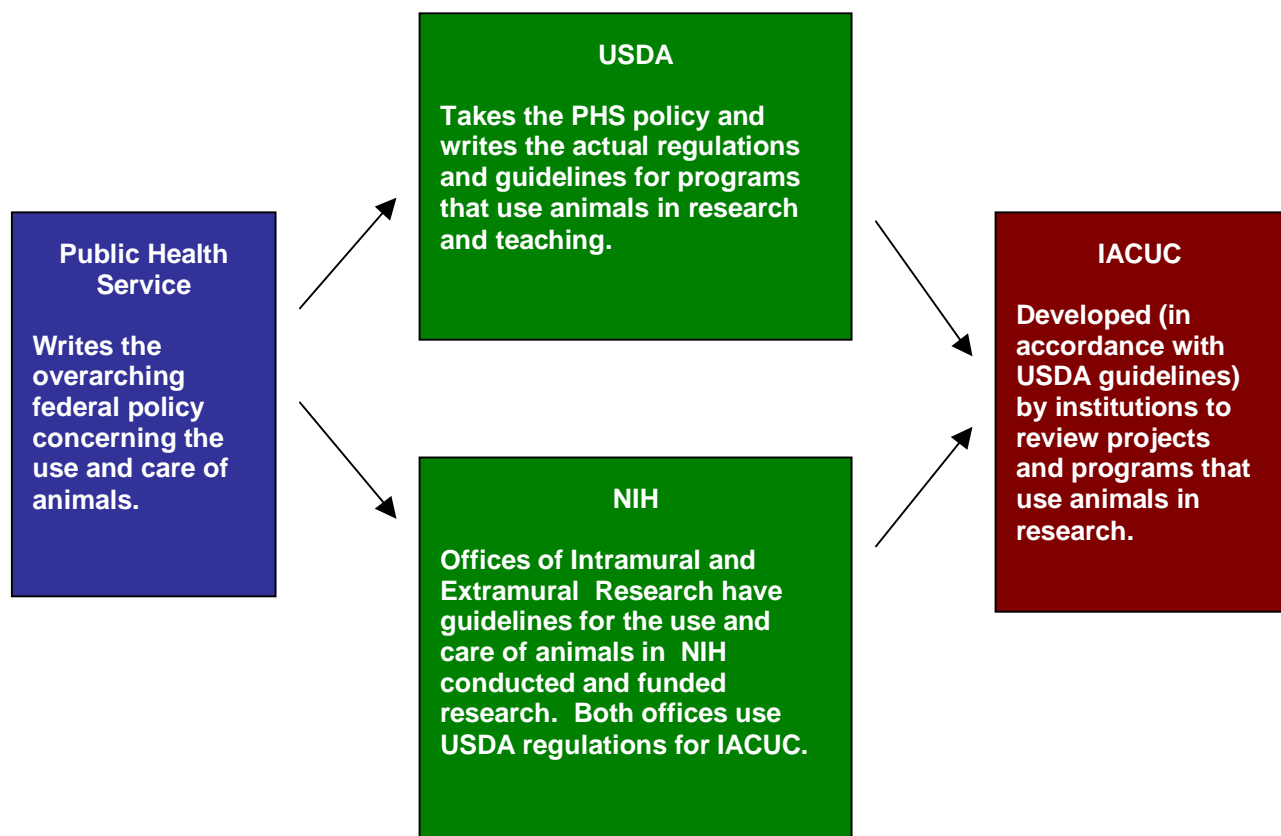
“(1) To insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment; (2) to assure the humane treatment of animals during transportation in commerce; and (3) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.”⁴⁵

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

- United States Department of Agriculture’s (**USDA**) Animal and Plant Health Inspection Service (**APHIS**) provides regulations and enforces the Public Health Service’s (**PHS**) Animal Welfare Act (**AWA**). The USDA is also responsible for issues dealing with non-research animals including: farm animals, companion animals, zoo animals, circus animals, and wildlife.
- The NIH Office of Extramural Research (**OER**) maintains the Office of Laboratory Animal Welfare (**OLAW**) and provides guidelines and regulations for the use of laboratory animals in research funded by NIH.
- NIH also has the Intramural Research Office of Animal Care and Use (**OACU**), which provides guidelines for research with animals conducted by NIH researchers.
- Institutional Animal Care and Use Committees (**IACUC**) are similar to Institutional Review Boards. IACUCs are hosted by institutions in accordance with the Animal Welfare Act to ensure ethical and humane treatment of animals used in research,

testing and teaching. The USDA provides guidelines and regulations for the operation of IACUCs.

The agencies above all overlap and interconnect. The USDA uses the policies dictated by PHS to write the regulations concerning the care and use of animals in research. The USDA also specifies the details for establishing an IACUC and how the IACUC should review projects and programs that use and care for animals. Projects and activities funded by the NIH must submit an “assurance” to the PHS that they have an IACUC and maintain ethical and humane treatment of animals involved in federally funded projects and activities in accordance with the AWA.



EXAMPLE CASE STUDY

Query 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?

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.

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES

- University of Minnesota Institutional Animal Care and Use Committee (IACUC) website: <http://www.research.umn.edu/subjects/animals/guide/printGuideAnimal.html>.

OTHER RESOURCES AND GUIDELINES

- The Animal Welfare Act website: <http://www.nal.usda.gov/awic/legislat/awa.htm>.
- The Animal Welfare Information Center website: <http://www.nal.usda.gov/awic/>.
- The National Institutes of Health Office of Animal Care and Use website: <http://oacu.od.nih.gov>
- The National Institutes of Health Office of Laboratory Animal Welfare website: <http://grants.nih.gov/grants/olaw/olaw.htm>.
- Public HS Policy on Humane Care and Use of Laboratory Animals last amended August, 2002 website: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>.
- A non-profit website to assist IACUCs throughout the United States: www.iacuc.org

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. This variety makes the topics surrounding research ethics with human subjects a challenging but important charge.

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.

The Belmont Report of 1979 outlines the three requirements for informed consent. The first requirement is that information disclosed to research 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.”⁴⁶

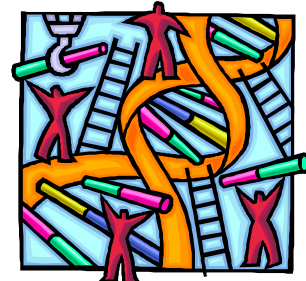
The second requirement for informed consent is comprehension. The concept of comprehension requires researchers to adapt information to be understandable to every participant. This requires taking into consideration different abilities, intelligence levels, maturity, and language needs.

Finally, the third requirement for informed consent is **voluntariness**. Informed consent can be neither coerced nor improperly pressured from any participant.⁴⁷

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.

Recently, a number of research projects have focused on unlocking genetic information. Genetic information may violate a person's right to privacy if not adequately protected. The very fact that genetic information contains information about identity provides a unique challenge to researchers. Many genetic experiments may seem harmless, but during the process of collecting genetic information on, for example, breast



cancer, a researcher will inevitably collect a wealth of other identifiable information that could potentially be linked to research participants as well.

The Health Information Portability and Accountability Act (HIPAA) passed into law in 1996 and went into effect in 2003. There are two main provisions in HIPAA. The first provision prevents workers and their families from losing health insurance when changing jobs. The second part of HIPAA is the Administrative Simplification Compliance Act (ASCA) and this part identifies issues in health information privacy and confidentiality. ASCA contains strict regulations concerning health information privacy, security (particularly of electronically stored health data), and personal identifiers attached to data. This is the strictest step taken thus far by the federal government to protect the vast amount of personal electronic health information maintained by health insurance companies, hospitals, clinics, researchers, and the government.

Risk benefit and beneficence. Beneficence is a principle used frequently in research ethics. It means, “doing good.”⁴⁸ Biomedical research strives to do good by studying diseases and health data to uncover information that may be used to help others – through the discovery of therapies that improve the lives of people with spinal cord injuries or new ways to prevent jaundice in infants. 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. 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. 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.

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 (article titles concerning each population appears below in *italics*):



1. MINORITY GROUPS

Gil EF. Bob S. Culturally competent research: an ethical perspective. Clinical Psychology Review, 1999; 19(1):45-55.

2. WOMEN

Stevens PE. Pletsch PK. Informed consent and the history of inclusion of women in clinical research. Health Care for Women International, 2002; 23(8):809-819.

3. MENTALLY IMPAIRED INDIVIDUALS

National Bioethics Advisory Commission Report. Research Involving Persons with Mental Disorders that may Affect Decision-Making Capacity. December 1998.
<http://www.georgetown.edu/research/nrcbl/nbac/capacity/TOC.htm>

4. CHILDREN

Allmark P. The ethics of research with children. Nurse Researcher, 2002; 10(2):7-19.

5. FINANCIALLY DISADVANTAGED INDIVIDUALS

Phoenix JA. Ethical considerations of research involving minorities, the poorly educated and/or low-income populations. Neurotoxicology & Teratology, 2002; 24(4):475-476.

6. DISADVANTAGED PEOPLE LIVING IN THIRD WORLD COUNTRIES

National Bioethics Advisory Commission Report. Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries. April 2001.

<http://www.georgetown.edu/research/nrcbl/nbac/pubs.html>

7. PRISONERS

Pasquerella L. Confining choices: should inmates' participation in research be limited? Theoretical Medicine & Bioethics, 2002; 23(6):519-536.

8. THE DECEASED

The deceased is included here as a population although deceased persons are not technically human subjects because human subjects are defined by 45 CF 46 as "living human beings."

Couzin J. Human subjects. Crossing a frontier: research on the dead. Science, 2003; 299(5603):29-30.

9. EMPLOYEES

Rose SL. Pietri CE. Workers as research subjects: a vulnerable population. Journal of Occupational & Environmental Medicine, 2002; 44(9):801-805.

Another potentially overburdened population who may contribute to research and assume risks, but the benefits are enjoyed by a separate group, is research that offers no hope of therapeutic assistance to participants, but may yield information for therapies for future generations or future sufferers. Biomedical research, by definition, does not have therapeutic benefit for participants as its goal. The goal of research is to advance knowledge and science. Some research does provide the additional benefit of providing potential therapeutic benefits to participants. This potential contributes to physician willingness to recruit their patients into a research project, and to the patient's willingness to participate. On the other hand, some research offers no potential for therapeutic benefit. In these cases, participants are being asked to put themselves in harm's way so that others in the future may benefit.



ETHICAL 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. Since that time, each set of regulations and internationally adopted principles concerning research with human subjects consider the following issues to be of tantamount concern:

- 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.
- 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 of people can be excluded from research or unfairly burdened unless there is an overwhelming reason to do so.

The way the federal government assures that research involving human subjects is conducted ethically is through the use of oversight by Institutional Review Boards (IRBs) housed within research institutions across the country.⁴⁹ The IRB review and approval process must be undertaken for all research projects that use human subjects in: a) institutions receiving federal funding; b) non-federally funded institutions that voluntarily opt to participate in the IRB review process; and, c) research results submitted to the FDA for consideration. Without IRB approval of these projects, research with human subjects at these institutions cannot move forward.

The IRB process was designed to catch potentially harmful projects before they got off the ground. It was also designed to think “globally” about ethical issues in research that may not necessarily be in the forethoughts of researchers’ minds. Questions

such as, “Is this research an appropriate use of federal resources?” or “Are women unfairly subjected to burden by this research question?” These questions are better addressed by people who are not as closely involved with the research.

Difficulty often arises when the IRB has to assess risks and benefits. For this reason, 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.

The Office of Human Subjects Research at NIH has a checklist designed to help IRBs weigh risks and benefits along with other helpful information, such as a decision tree tool (see below) on their website: <http://206.102.88.10/ohsr/site/irb/tree.html>

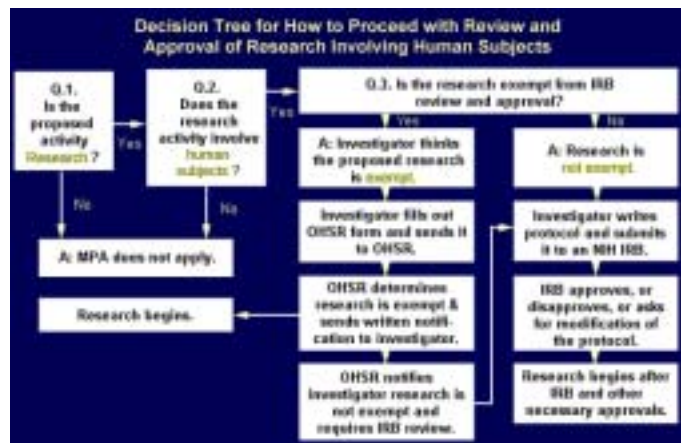
IRB MISSION

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

- a) Balances potential risk to the participants with anticipated benefits,
- b) Offers protection to participants from unnecessary harm,
- c) Offers proportional compensation to participants,
- d) The person in charge of the research is a qualified scientist, and
- e) 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/ohsr/site/index> (3/11/03).

Research Project Review Decision Tree from the NIH IRB website:*



* National Institutes of Health Office of Human Subjects Research website. <http://206.102.88.10/ohsr/site/irb/tree.html>. Accessed 3/11/03.

The Protection of Human Subjects in the Public Health Act (45 CFR 46), in addition to establishing the nuts and bolts for IRBs, also specifies regulations for research involving pregnant women subjects, fetuses, children, and prisoners. The regulations and guidelines are on the NIH website: <http://206.102.88.10/ohsrsite/guidelines/45cfr46.html>.

Regulations on research with human subjects are also impacted by the HIPAA guidelines and regulations designed to protect individual health information and improve information exchange. The regulations can be broken down into four parts:

- 1) Electronic information exchange and code sets
www.cms.hhs.gov/hipaa/hipaa2/regulations/transactions/default.asp#finalrule
- 2) Security
www.cms.hhs.gov/hipaa/hipaa2/regulations/security/default.asp#finalrule
- 3) Unique identifiers
www.cms.hhs.gov/hipaa/hipaa2/regulations/identifiers/default.asp
- 4) Privacy
www.cms.hhs.gov/hipaa/hipaa2/regulations/privacy/default.asp#finalrule

EXAMPLE CASE STUDY

Query Mike's physician has asked him to participate in a research project. What should Mike know before he consents?

Answer Mike should be asked first to consent to participate in the research project. The consent process should tell him everything he needs to know about the project including: possible risks, expected benefits (when applicable), and protections for his privacy and confidentiality. If Mike's physician doesn't explain these things thoroughly to Mike, he should request more information or reconsider his participating. Mike should only consent to participate if he: a) understands all the information as presented to him; b) feels that he is voluntarily consenting to participate of his own free will; and, c) feels that he is free to drop out of the study at any time.

UNIVERSITY OF MINNESOTA RESOURCES AND GUIDELINES⁵⁰

- University of Minnesota Office of Sponsored Projects Administration website:
<http://www.ospa.umn.edu/>
- University of Minnesota IRB website: <http://www.irb.umn.edu/>
- University of Minnesota Privacy and Security Project:
http://www.ahc.umn.edu/ahc_content/about/privacy/
- On-line instructional materials for human subject research:
<http://www.research.umn.edu/ethics/>

OTHER RESOURCES AND GUIDELINES

- NIH Office of Human Subjects Research (OHSR) website:
<http://206.102.88.10/ohsr/site/index.html>
- World Health Organization (WHO) Research Ethics with Human Subjects website:
<http://www.who.int/ethics/research/en/>
- Department of Health and Human Services Office for Human Research Protections (OHRP) website: <http://ohrp.osophs.dhhs.gov/>
- Department of Health and Human Services Office for Civil Rights HIPAA information:
<http://www.hhs.gov/ocr/hipaa/finalreg.html>

GLOSSARY OF CLINICAL TRIAL TERMS

The following glossary is reprinted from www.clinicaltrials.gov.

ADVERSE REACTION: (Adverse Event.) An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time (See [Side Effects](#)).

ADVOCACY AND SUPPORT GROUPS: Organizations and groups that actively support participants and their families with valuable resources, including self-empowerment and survival tools.

APPROVED DRUGS: In the U.S., the Food and Drug Administration (FDA) must approve a substance as a drug before it can be marketed. The approval process involves several steps including pre-clinical laboratory and animal studies, clinical trials for safety and efficacy, filing of a New Drug Application by the manufacturer of the drug, FDA review of the application, and FDA approval/rejection of application (See [Food and Drug Administration](#)).

ARM: Any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more (See [Randomized Trial](#)).

BASELINE: 1. Information gathered at the beginning of a study from which variations found in the study are measured. 2. A known value or quantity with which an unknown is compared when measured or assessed. 3. The initial time point in a clinical trial, just before a participant starts to receive the experimental treatment which is being tested. At this reference point, measurable values such as CD4 count are recorded. Safety and efficacy of a drug are often determined by monitoring changes from the baseline values.

BIAS: When a point of view prevents impartial judgment on issues relating to the subject of that point of view. In clinical studies, bias is controlled by blinding and randomization (See [Blind](#) and [Randomization](#)).

BLIND: A randomized trial is "Blind" if the participant is not told which arm of the trial he is on. A clinical trial is "Blind" if participants are unaware on whether they are in the experimental or control arm of the study; also called masked. (See [Single Blind Study](#) and [Double Blind Study](#)).

CLINICAL: Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

CLINICAL ENDPOINT: See [Endpoint](#).

CLINICAL INVESTIGATOR: A medical researcher in charge of carrying out a clinical trial's protocol.

CLINICAL TRIAL: A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed. (See [Phase I, II, III, and IV Trials](#)).

COHORT: In epidemiology, a group of individuals with some characteristics in common.

COMMUNITY-BASED CLINICAL TRIAL (CBCT): A clinical trial conducted primarily through primary-care physicians rather than academic research facilities.

COMPASSIONATE USE: A method of providing experimental therapeutics prior to final FDA approval for use in humans. This procedure is used with very sick individuals who have no other treatment options. Often, case-by-case approval must be obtained from the FDA for "compassionate use" of a drug or therapy.

COMPLEMENTARY AND ALTERNATIVE THERAPY: Broad range of healing philosophies, approaches, and therapies that Western (conventional) medicine does not commonly use to promote well-being or treat health conditions. Examples include acupuncture, herbs, etc. Internet Address: <http://www.nccam.nih.gov>.

CONFIDENTIALITY REGARDING TRIAL PARTICIPANTS: Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical information. The trial participants' consent to the use of records for data verification purposes should be obtained prior to the trial and assurance must be given that confidentiality will be maintained.

CONTRAINDICATION: A specific circumstance when the use of certain treatments could be harmful.

CONTROL: A control is the nature of the intervention control.

CONTROL GROUP: The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo (See [Placebo](#) and [Standard Treatment](#)).

CONTROLLED TRIALS: Control is a standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.

DATA SAFETY AND MONITORING BOARD (DSMB): An independent committee, composed of community representatives and clinical research experts, that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

DOSE-RANGING STUDY: A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.

DOUBLE-BLIND STUDY: A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called double-masked study. See [Blinded Study](#), [Single-Blind Study](#), and [Placebo](#).

DOUBLE-MASKED STUDY: See [Double-Blind Study](#).

DRUG-DRUG INTERACTION: A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

DSMB: See [Data Safety and Monitoring Board](#).

EFFICACY: (Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the procedure mandated by the FDA, Phase II clinical trials gauge efficacy, and Phase III trials confirm it (See [Food and Drug Administration \(FDA\)](#), [Phase II](#) and [III Trials](#)).

ELIGIBILITY CRITERIA: Summary criteria for participant selection; includes Inclusion and Exclusion criteria. (See [Inclusion/Exclusion Criteria](#))

EMPIRICAL: Based on experimental data, not on a theory.

ENDPOINT: Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

EPIDEMIOLOGY: The branch of medical science that deals with the study of incidence and distribution and control of a disease in a population.

EXCLUSION/INCLUSION CRITERIA: See [Inclusion/Exclusion Criteria](#).

EXPANDED ACCESS: Refers to any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants who are failing on currently available treatments for their condition and also are unable to participate in ongoing clinical trials.

EXPERIMENTAL DRUG: A drug that is not FDA licensed for use in humans, or as a treatment for a particular condition (See [Off-Label Use](#)).

FDA: See [Food and Drug Administration](#).

FOOD AND DRUG ADMINISTRATION (FDA): The U.S. Department of Health and Human Services agency responsible for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices, including those used in the diagnosis, treatment, and prevention of HIV infection, AIDS, and AIDS-related opportunistic infections. The FDA also works with the blood banking industry to safeguard the nation's blood supply. Internet address: <http://www.fda.gov/>.

HYPOTHESIS: A supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation.

INCLUSION/EXCLUSION CRITERIA: The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

IND: See [Investigational New Drug](#).

INFORMED CONSENT: The process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.

INFORMED CONSENT DOCUMENT: A document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

INSTITUTIONAL REVIEW BOARD (IRB): 1. A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they begin. 2. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants.

INTENT TO TREAT: Analysis of clinical trial results that includes all data from participants in the groups to which they were randomized (See [Randomization](#)) even if they never received the treatment.

INTERVENTION NAME: The generic name of the precise intervention being studied.

INTERVENTIONS: Primary interventions being studied: types of interventions are Drug, Gene Transfer, Vaccine, Behavior, Device, or Procedure.

INVESTIGATIONAL NEW DRUG: A new drug, antibiotic drug, or biological drug that is used in a clinical investigation. It also includes a biological product used *in vitro* for diagnostic purposes.

IRB: See [Institutional Review Board](#).

MASKED: The knowledge of intervention assignment. See [Blind](#)

NATURAL HISTORY STUDY: Study of the natural development of something (such as an organism or a disease) over a period of time.

NEW DRUG APPLICATION (NDA): An application submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed - for a license to market the drug for a specified indication.

OFF-LABEL USE: A drug prescribed for conditions other than those approved by the FDA.

ORPHAN DRUGS: An FDA category that refers to medications used to treat diseases and conditions that occur rarely. There is little financial incentive for the pharmaceutical industry to develop medications for these diseases or conditions. Orphan drug status, however, gives a manufacturer specific financial incentives to develop and provide such medications.

PEER REVIEW: Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations.

PHARMACOKINETICS: The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

PHASE I TRIALS: Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

PHASE II TRIALS: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.

PHASE III TRIALS: Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.

PHASE IV TRIALS: Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

PLACEBO: A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment. No sick participant receives a placebo if there is a known beneficial treatment. (See [Placebo Controlled Study](#)).

PLACEBO CONTROLLED STUDY: A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.

PLACEBO EFFECT: A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

PRECLINICAL: Refers to the testing of experimental drugs in the test tube or in animals - the testing that occurs before trials in humans may be carried out.

PREVENTION TRIALS: Refers to trials to find better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.

PROTOCOL: A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment (See [Inclusion/Exclusion Criteria](#)).

QUALITY OF LIFE TRIALS (or Supportive Care trials): Refers to trials that explore ways to improve comfort and quality of life for individuals with a chronic illness.

RANDOMIZATION: A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant (See [Arm](#)).

RANDOMIZED TRIAL: A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilized. (See [Arm](#) and [Placebo](#)).

RISK-BENEFIT RATIO: The risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated.

SCREENING TRIALS: Refers to trials which test the best way to detect certain diseases or health conditions.

SIDE EFFECTS: Any undesired actions or effects of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects (See [Adverse Reaction](#)).

SINGLE-BLIND STUDY: A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking; also called single-masked study. (See [Blind](#) and [Double-Blind Study](#)).

SINGLE-MASKED STUDY: See [Single-Blind Study](#).

STANDARD TREATMENT: A treatment currently in wide use and approved by the FDA, considered to be effective in the treatment of a specific disease or condition.

STANDARDS OF CARE: Treatment regimen or medical management based on state of the art participant care.

STATISTICAL SIGNIFICANCE: The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.

STUDY ENDPOINT: A primary or secondary outcome used to judge the effectiveness of a treatment.

STUDY TYPE: The primary investigative techniques used in an observational protocol; types are Purpose, Duration, Selection, and Timing.

TOXICITY: An adverse effect produced by a drug that is detrimental to the participant's health. The level of toxicity associated with a drug will vary depending on the condition which the drug is used to treat.

TREATMENT IND: IND stands for Investigational New Drug application, which is part of the process to get approval from the FDA for marketing a new prescription drug in the U.S. It makes promising new drugs available to desperately ill participants as early in the drug development process as possible. Treatment INDs are made available to participants before general marketing begins, typically during Phase III studies. To be considered for a treatment IND a participant cannot be eligible to be in the definitive clinical trial.

TREATMENT TRIALS: Refers to trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

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