**RESEARCH ETHICS**

Research ethics provides guidelines for the responsible conduct of research. In addition, research ethics educates and monitors researchers to ensure a high ethical standard.

The Nuremberg Code consisted of ten basic ethical principles/guidelines 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.

The unique principles developed within the Helsinki Declaration include:

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

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 Behavioural 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)

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

***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** 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. 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. 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. 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.

**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 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. 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.

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

1. “Quotes another person’s actual words, either oral or written;
2. Paraphrases another person’s words, either oral or written;
3. Uses another person’s idea, opinion, or theory; or
4. 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. 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. To avoid unintentional or accidental plagiarizing of another person’s work, use the following tips:

1. Cite all ideas and information that is not your own and/or is not common knowledge,
2. Always use quotation marks if you are using someone else’s words,
3. At the beginning of a paraphrased section, show that what comes next is someone else’s original idea,
4. At the end of a paraphrased section, place the proper citation.

**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.

A high-quality peer review should evaluate a publication on the following merits:

1. Importance – Does the research impact health and health care?
2. Usefulness – Does the study provide useful scientific information?
3. Relevance – Does the research apply to the journal’s readers and content area of interest?
4. Sound methods – Was the research conducted with sound scientific methods that allowed the researchers to answer their research question?
5. Sound ethics – Was the study conducted ethically ensuring proper protection for human subjects? Were results reported accurately and honestly?
6. Completeness – Is all information relevant to the study included in the article?
7. Accuracy – Is the written product a true reflection of the conduct and results of the research?

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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.

**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.

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. 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.

**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.

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:

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

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.

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:

1. 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.)
2. How will data be collected? (Will data be collected via phone, mail, personal interview, existing records, secondary sources, etc.?)
3. Will there be identifying information within the data? If yes, why? How will this be rectified?
4. 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.?)
5. Who will ensure that no data were excluded from the final results and ensure accuracy of result interpretation?
6. 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.

**Research misconduct** is the process of identifying and reporting unethical or unsound research. The United States’ Office of Scientific and Technology Policy (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.

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.

In addition to defining research misconduct, a finding of research misconduct requires that:

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

Research misconduct can be the result of criminal behaviour. 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 and the process of peer review helps to maintain and safeguard scientific integrity.

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.