

Ethics in Research: An Overview for Novice Researchers

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Research studies involving human participants must be approved by the organization's Institutional Review Board before data collection can begin. To a frustrated novice researcher who is struggling to obtain approval, this process can, at times, feel excessively rigorous. Inhumane and unethical experiments from the past have driven the evolution of research ethics regulations. Understanding the past and present requirements of ethical research helps novice and seasoned researchers alike to better appreciate the process. This paper will briefly introduce the history, landmark reports, current regulations, and ethical issues when conducting and publishing research that includes human subjects.

Keywords: ethics, institutional review board, human subjects, research, informed consent, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report, The Common Rule

INTRODUCTION

Ethics in research has evolved significantly over the last 100 years, from the horrific beginnings of human experimentation to criminal punishment for those atrocities, to federal oversight to prevent reoccurrences. This paper will provide a brief overview of the history of ethics in research and the current regulations. Understanding the history of human research can help put the present regulations into context. This understanding is important because researchers of all experience levels must adhere to ethical standards.

HISTORY OF ETHICS IN RESEARCH

The first half of the 20th century saw many egregious horrors occur in the name of science. The Willowbrook Study infected institutionalized intellectually disabled children with hepatitis from 1956 to 1971 in an attempt to study the viral infection (Krugman, 1986). The Fernald and Wrentham State schools fed radioactive oatmeal to disabled and abandoned young boys in the 1950s to study digestion (West, 2008). The 40-year Tuskegee syphilis study deceived over 600 African American men into the study, then withheld treatment, even as many of them suffered from severe sickness or died (Brown, 2017). In a study of cancer-killing viruses, Ohio State Penitentiary prison inmates were unknowingly injected with cancer cells in the 1950s and '60s (Vernon, 2020). In the 1940s, American scientists infected patients with mental health conditions and prisoners in Guatemala with sexually transmitted diseases to test the effectiveness of penicillin (Rodriguez & Garcia, 2013). These few examples of unethical studies are particularly horrific in part because they occurred after The Nuremberg Code was in place, the landmark document that describes ethical principles when working with human subjects (Ezekiel et al., 2008, p. 136).

The Nuremberg Code

The year following the end of World War II, 1946, proceedings were held in Nuremberg, Germany, to hold Nazis accountable for war crimes and crimes against humanity; these are known as the Nuremberg Trials (Ghooi, 2011). The trial of USA v. Brandt, known as the Doctors Trial, tried 20 Nazi doctors and three administrators for the lethal human experiments they conducted on prisoners of war. At the end of the trial in 1947, the judges sent forward The Nuremberg Code, a 10-point set of rules designed to protect the rights of research subjects (Ezekiel et al., 2008, p. 138). One of the main strengths of this code is the inclusion of informed consent, insisting that the “voluntary, competent, informed, and understanding consent of the research subject is a necessary (but not sufficient) prerequisite of lawful human experimentation.” The Nuremberg Code was adopted as a doctrine by the United States Defense Department in 1953, although it was classified as top secret until 1975. The Nuremberg Code is a building block that influenced the creation of another foundational document on ethics in medical research, The Declaration of Helsinki.

The Declaration of Helsinki

The Declaration of Helsinki is a set of ethical principles first published by The World Medical Association in 1964 (Carlson et al., 2004). The Declaration of Helsinki differs from The Nuremberg Code by emphasizing physicians’ and researchers’ obligations to their subjects (Shuster, 1997). The declaration includes the following requirements:

- An impartial committee should assess the research plans before the start of the project.
- Informed consent from every participant is required.
- Only qualified individuals should conduct research.
- Research that uses human subjects should be based on lab or animal research.
- The risks of participating in research should not outweigh the benefits. (Mandal et al., 2011)

The Declaration of Helsinki has been revised several times. In 2013, it was revised to expand informed consent to include significant others or other community members, which acknowledges that in some instances, informed consent needs to include others as well as the participant, such as family members or community leaders (Ndebele, 2013). Other additions to the 2013 revision include compensation for injuries resulting from trial participation and using placebos in research. The next revision of the Declaration of Helsinki is expected to be considered by Council and the General Assembly in Helsinki in October 2024. The Declaration of Helsinki is a set of guidelines for physicians and researchers, but a subsequent set of ethical principles will instead focus on research design and publication, The Belmont Report.

The Belmont Report

The National Research Act of 1974 created The National Commission for the Protection of Human Services of Biomedical and Behavioral Research. This commission wrote The Belmont Report, which summarizes ethical principles for using human subjects for research (Moon, 2009). The report defines *Research* as “an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge” (U.S. Department of Health & Human Services, 1979). This report aimed to “identify the basic ethical principles that should underlie the conduct of research involving human subjects” (Sims, 2010).

The Belmont Report, first published in 1979, lays out three basic principles for safeguarding the rights of human subjects in research: 1) Beneficence, 2) Justice, and 3) Respect for Persons (Sims, 2010). Beneficence requires that an assessment of the benefits of the research is weighed against the potential risks. Research subjects must be informed of all potential risks. This principle incorporates the “first do no harm” philosophy. The Justice principle requires fair treatment for all and forbids exploiting vulnerable participants, such as minorities or economically disadvantaged groups. The final principle, Respect for Persons, states that all individuals are autonomous agents and can decide for themselves if they want to participate in research, if they do not, and if they want to withdraw from a study. All efforts must be made to obtain informed consent from participants or proxy agents via a signed document containing

comprehensible language. The Belmont Report's three ethical principles, 1) Beneficence, 2) Justice, and 3) Respect for Persons, are the basis for The Common Rule's procedural requirements.

The Common Rule

The Common Rule was established in 1966 as a policy for Public Health Service funding in response to the exploitation of participants in scientific research in the United States (Dingwall, 2017). This guideline was formalized as a health department regulation in 1974, following more cases of abuse. It was initially adopted in 1991 as a framework by most federal agencies in the United States that commission or support research projects. The Common Rule mandates that an independent ethics evaluation is required for all federally funded research initiatives that involve human subjects before they can begin (Metcalf, 2016). It establishes a legal foundation for the work of Institutional Review Boards that regulate the ethical elements of federally supported research (Dingwall, 2017).

The Common Rule is not without criticism, though. Social Scientists have complained that all forms of human subject research are lumped together under The Common Rule when they do not all contain the same risks or benefits, making social science research excessively scrutinized (Metcalf, 2016). When addressing the fact that social science and biomedical research both endure the same IRB approval process, Dingwall (2017) argues, "No one will inject them with substances that could prove irreversibly toxic or deny them potentially life-saving benefits by randomization into a control group. Social science data is often collected in public settings or from administrative records". The Common Rule was last updated in 2018; many social scientists hope this concern will be addressed in future revisions.

INSTITUTIONAL REVIEW BOARDS

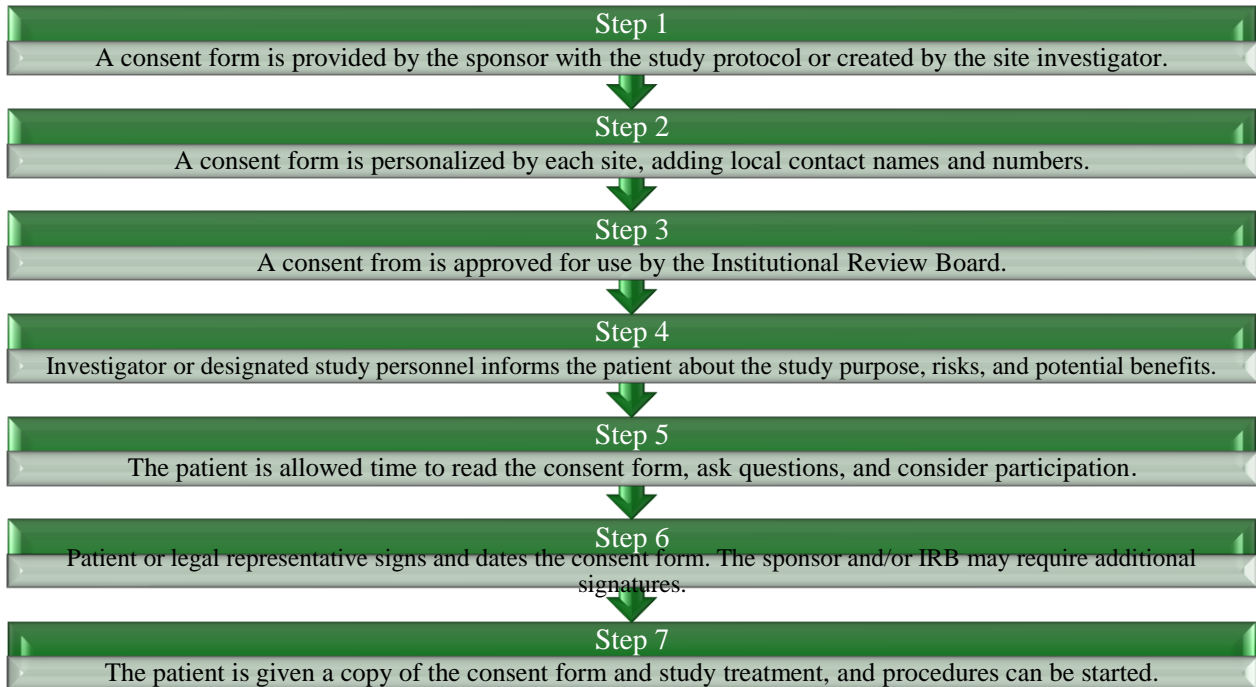
In 1979, The U.S. Department of Health, Education, and Welfare mandated that all research involving human subjects be assessed to ensure that participants are protected from physical and emotional harm (SUNY Canton, 2022). The committee that ensures this mandate is adhered to is the Institutional Review Board (IRB). The role of the IRB is to examine and approve proposals for human subject research to ensure that their rights and well-being are protected before the research begins (Khin-Maung-Gyi, 2009). IRBs have the authority to approve, reject, or request changes to sections of applications before approving the research to proceed. The regulations outline the following criteria, which IRBs refer to when evaluating project applications:

- Risks to subjects is minimized.
- Only includes risks to subjects that are acceptable in comparison to any expected benefits.
- Ensure subjects' rights are respected by requiring that each subject, or their proxy agent, provide informed and voluntary consent that is properly documented.
- Ensure subjects are selected fairly.
- Ensure adequate provisions for monitoring the research are included within the research plan.
- Ensure suitable provisions are in place that protect the confidentiality and privacy of the subjects.
- Ensure extra precautions are incorporated when some or all subjects are vulnerable to coercion or improper influence. (Khin-Maung-Gyi, 2009)

Informed Consent

The Nuremberg Code, The Declaration of Helsinki, and The Belmont Report all include the concept of informed consent. Informed consent is the process whereby all potential research subjects are informed about all aspects of the research to help the individual decide whether or not they wish to take part and confirm their willingness to participate in the study (Nijhawan et al., 2013). Consent is obtained by notifying the individual of their rights, the study's objective, procedures, potential risks and benefits, projected duration, degree of confidentiality of personal identity, and demographic data. Figure 1 illustrates the flow chart for obtaining informed consent. Figure 1

**FIGURE 1
FLOW CHART OF THE INFORMED CONSENT PROCESS**



Note: Adapted from Nijhawan et al. (2013)

Research Noncompliance

Research noncompliance can be a serious offense and may include protocol violations. Research noncompliance is failing to follow the research plan, IRB requirements, federal and state regulations, or institutional policies regarding research that involve human subjects (Lapid et al., 2019). Serious noncompliance may harm the subjects or compromise the study’s integrity and validity. A protocol violation is any change in the study’s plan that IRB has not approved. Unanticipated problems, or unexpected events related to the participants that could put them in physical or mental harm, must be reported immediately to IRB. Delays in reporting unanticipated problems may be considered noncompliance. Unanticipated problems generally require corrective action to ensure the safety of the participants (Lapid et al., 2019).

ETHICAL ISSUES IN RESEARCH WITH HUMAN SUBJECTS

A researcher must consider several ethical issues when creating their research design; three not yet addressed in this paper are conflicts of interest, undue influence, and cultural differences.

Conflicts of Interest

For researchers, conflicts of interest are instances in which the impartiality of a study may be compromised because the researcher stands to benefit from the conclusions reached (Dunn et al., 2016). One category of conflicts of interest is financial. When a researcher has a financial interest in their study’s outcome, their professional judgment can be compromised, along with the study’s validity (Bittker, 2021).

One example of a researcher with a financial conflict of interest is Dr. Willie Wei-Hock Soon. Dr. Soon was working for the Harvard-Smithsonian Center for Astrophysics when he and Sallie Baliunas published a paper claiming that the 20th century was not the warmest century or had the most extreme weather of the past millennium, ultimately denying global warming. The controversy of this situation was that Soon and

Baliunas received a portion of their funding from the gas and oil industry, and they failed to disclose this conflict of interest (Gillis & Schwartz, 2015).

Other conflicts of interest include personal or professional relationships or working for competitors. Dunn et al. (2016) assert that “conflicts of interest remain underreported, inconsistently described, and difficult to access.” Advances are being made to make conflicts of interest more transparent in medical research, including publicly accessible registries that disclose interests and databases of clinical trials (Dunn et al., 2016).

Undue Influence

The socioeconomic struggles some areas face, such as lack of food and water, lack of access to healthcare, and lack of education, can make them more susceptible to exploitation. The Declaration of Helsinki states that research in vulnerable communities can occur only when “the research is responsive to the health needs or priorities of this group, and the research cannot be carried out in a non-vulnerable group” (*World Medical Association*, 2018). Ethical studies must be well planned, and the benefits must be available to the host community (Bittker, 2021).

Cultural Differences

Researchers can work across a wide range of cultures. One ethical issue that can arise when dealing with human subjects is cultural differences between the subjects and the researcher. Out of “respect for persons,” it is crucial that a researcher include potential cultural differences in the research design. Bittker (2021), giving an example of a cultural difference experienced, states that in “cultures where individualism is inconsequential, collective decision-making will be a better standard for consent.”

ETHICAL ISSUES IN REPORTING RESEARCH FINDINGS

Reporting research findings should be an objective process, free from bias. Researchers should avoid scientific misconduct in research; however, researchers can face external pressure, which may influence the reporting of accurate data. Marco and Larkin (2008) list several examples of unethical decisions researchers must resist when reporting findings:

- Inaccurate reporting of missing data points
- Not reporting all pertinent data
- Failing to report the number of eligible participants
- Failing to report negative findings
- Being influenced by researched sponsors
- Inappropriately labeling graphs to magnify minor differences
- Reporting percentages rather than actual numbers with the intent to deceive
- Inappropriately applying statistical tests and reporting only the favorable results
- Reporting differences, although no statistical difference has been found
- Splitting data into multiple reports merely for the sake of increasing publications
- Using terminology without providing concise definitions, such as “rarely” or “commonly”
- Reporting conclusions that are not supported by data
- Exaggerating research results for publicity
- Ignoring previous work that challenges the conclusions

CONCLUSION

Understanding the history of human subjects research and the current regulations can help novice researchers navigate the process of receiving IRB approval. This understanding is important because all researchers must adhere to ethical standards. This paper has provided a brief introduction to the history,

landmark reports, current regulations, and ethical issues when conducting and reporting research which includes human subjects.

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