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PROTECTING PARTICIPANTS OF SOCIAL SCIENCE RESEARCH

ILLINOIS CRIMINAL JUSTICE INFORMATION AUTHORITY
CENTER FOR JUSTICE RESEARCH AND EVALUATION

LILY GLEICHER, PH.D., RESEARCH ANALYST

Abstract: Social science research, rooted in the scientific method, is the foundation on which to advance knowledge and society. Part of research can include the participation of individuals, or "human subjects," to help further the understanding of society and issues within society. International, federal, state, and local regulations ensure individuals are protected from harm while participating in research. Federally-funded individuals and agencies, including the Illinois Criminal Justice Information Authority, adhere to these regulations. This article provides an overview of federal regulations for human subject research protections in social science.

Introduction

Research rooted in the scientific method helps inform stakeholders, policymakers, programs, and the community at large; it is the foundation on which to prove or disprove theory, understand issues, build knowledge, and advance society. In social science research, individuals may be asked to participate in studies as "human subjects" to help increase knowledge and understanding on various topics. Individuals may agree to participate in focus groups, interviews, surveys, observations for research studies and program evaluations. While individual participation can provide numerous social and individual benefits and improve the application of programs and practices, researchers must take ethical considerations into account when developing and conducting a study involving human subjects.

> *"Research means a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**."*
> *-45 CFR 46.102(l)*

In the United States, human subject research has become more strictly regulated through local, state, and federal laws; however, federal regulations only apply to those research studies that receive federal funding.[1] While regulatory requirements may vary by locale and funding sources, the primary responsibility for conducting ethical research lies with researchers and staff involved in carrying out their studies.[2]

> *"**Human subjects** are living individuals about whom an investigator (whether professional or student) conducting research:1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.*
> *-45 CFR 46.102(e)(1)*

Research norms vary from field to field, but there are several shared values that bind all researchers together include: honesty, accuracy, efficiency, and objectivity.[3] Responsible research adheres to these values, in addition to professional codes, government regulations and guidelines, institutional policies and guidelines, and personal responsibility.[4]

History of National and International Research Abuses

Many current principles, practices, and codifications of ethical and legal human subject research stem from a series of unethical, abusive, and harmful research involving humans—sometimes participating in research involuntarily or without their consent.[5] A series of social and medical research abuses, most notably stemming from World War II, led to a system of both international and federal ethical protections to better shield individuals from potential harm.[6] These international and federal regulating bodies have developed—and continue to critically review and revise—regulations related to human subjects research.

Two notable historical cases of research abuses that contributed to more critical examination of ethical standards for human subject research and deceitful research practices are The Nuremberg War Crime Trials and The Tuskegee Syphilis Study.[7]

- **The Nuremberg War Crime Trials**, held in the mid- to late-1940s, publicly exposed torturous and fatal involuntary human experiments conducted by Nazi physicians and scientists on prisoners in Nazi concentration camps.[8] This led to the development of the Nuremberg Code and the Declaration of Helsinki.

- **The Tuskegee Syphilis Study**, which began in 1932 and spanned decades, was conducted by the Tuskegee Institute (now Tuskegee University) and the U.S. Public Health Service. The study experimented on Black men with and without syphilis in Macon County, Ala., to document the natural progression of syphilis.[9] Study participants were not advised of their right to quit the study, informed of the study's real purpose, nor offered an effective treatment for the deadly illness, which was penicillin, available in 1947.[10] This led to more explicit government regulation regarding the well-being of human subjects as part of research.

Historical cases indicate unethical practices also were performed during prestigious medical and behavioral studies on children with intellectual disabilities, cognitively impaired patients, and prisoners in correctional facilities.[11]

Responses to Historical Research Abuse

The Nuremberg Code

To address the use of inhumane research as documented in World War II, the Nuremberg Code explicitly detailed guidelines for the ethical treatment of human subjects in research.[12] The Nuremberg Code consists of a set of directives for ethical human experimentation that focus on:

- Voluntary consent of the human subjects, with the liberty to disengage from research at any point of a study.
- Experimentation for societal good, that cannot be conducted by other means, and attempts to yield fruitful results.
- Research conducted, designed, and prepared in such a way to avoid all unnecessary physical or mental pain and suffering, injury, disability, or death.
- Studies conducted by scientifically qualified individuals.
- Researchers exercising good faith and superior skill and judgement, who are prepared to terminate experimentation if continuation is likely to result in injury, disability, and/or death.
- Research benefits that outweigh the risks.[13]

While the Nuremberg Code was not formally adopted by the U.S. government, it was an influential, international document which formed the basis of current human subject research policies.[14]

Federal Regulations for Research Using Human Subjects

The Tuskegee Institute's syphilis study was stopped by an advisory panel created by the U.S. government in 1972.[15] Soon thereafter, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created (herein referred to as the commission) in 1974.[16] In addition, Congress required the then-Department of Health, Education, and Welfare (currently the U.S. Department of Health and Human Services) to create and clarify regulations regarding human subject research in the United States.[17]

The commission developed policies to protect human subjects of research studies, including a general policy for protection of human research subjects: Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46).[18] In addition, the commission created additional guidelines through subparts B through D of 45 CFR 46 that protect vulnerable populations.[19]

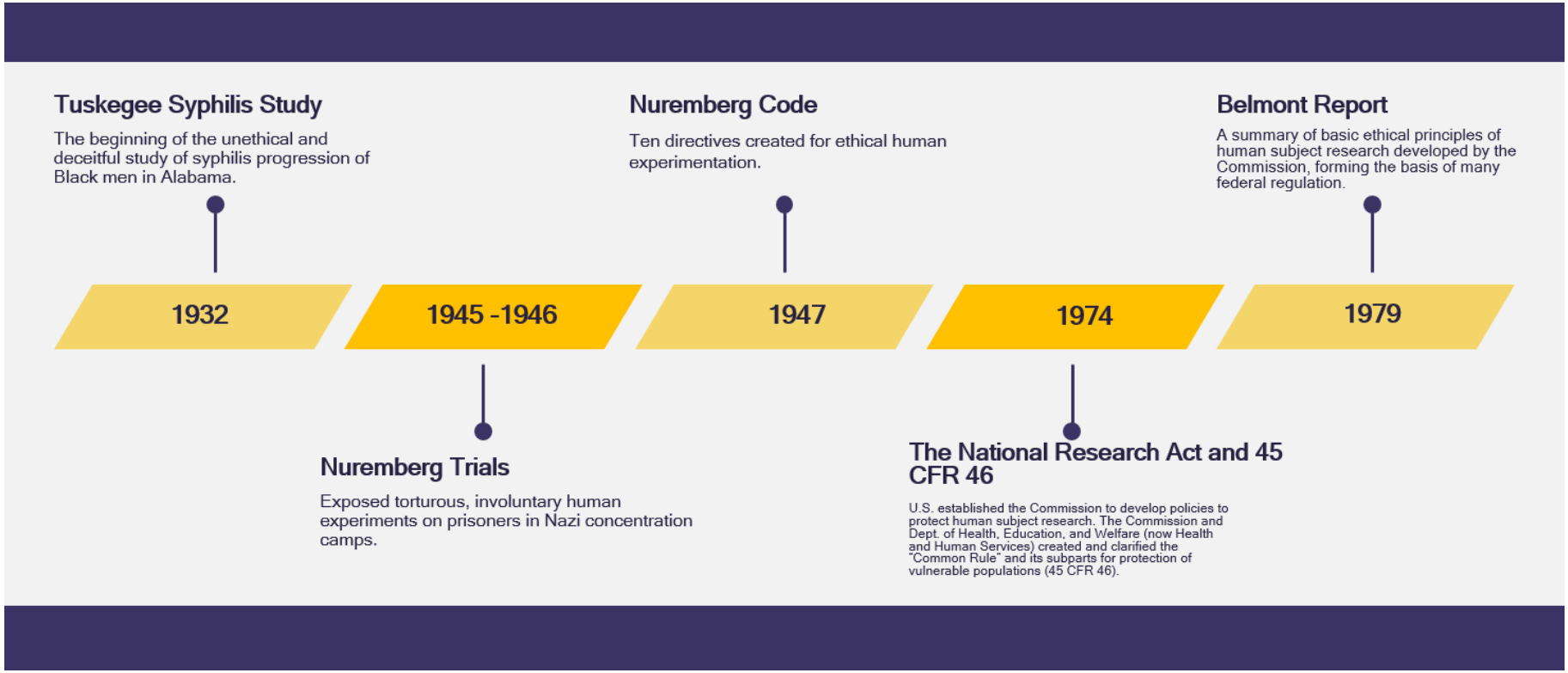
The commission also provided guidelines regarding reviews of research processes and protocols, disclosure of information, confidentiality and privacy, risks and benefits of research, institutional review board processes, and research compensation.

Belmont Report. Published by the commission in 1978, the Belmont Report summarizes the basic ethical principles to guide human subject research, outlining the principles that help inform moral judgements on fairness, appropriateness, and adequacy of the protections provided to human subjects as part of research.[20] The Belmont Report prescribed three basic principles to guide the decision-making process when conducting ethical human subject research: *respect for persons, beneficence,* and *justice.*[21] These principles are the accepted and common standard for decisions made by institutional review boards (IRBs), administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities.[22]

- **Respect for persons**. Researchers should respect the autonomy of opinions and choices of people, refraining from potentially influencing a person's decision to participate in research, with additional protections for individuals with limited autonomy.[23] This includes information on protocols of obtaining consent in addition to the voluntariness of that consent.
- **Beneficence**. Researchers should minimize the harm and maximize the benefits to those persons involved in research. This, however, does not mean that study participants are not exposed to potential risks, though potential risks must be justified based on the research's potential benefits to the individual, society, and/or knowledge.[24]
- **Justice**. Researchers are obligated to select subjects equitably, and equally distribute the burdens and benefits of research.[25] Thus, researchers cannot exploit specific groups of people due to those individuals' circumstances (e.g. poor, prisoners).[26] Researchers should critically evaluate whether subject selection is systematically selecting more vulnerable populations due to ease of access, ability to manipulate, or due to individuals' compromised position (e.g. prisoners) and not for reasons linked to the actual research study questions.[27]

Figure 1.

Timeline of Human Subject Research Events



Source: Cohen, J. M. (2017). *History and ethics of human subjects research.* Collaborative Institutional Training Initiative (CITI) Program.; Steneck, N. H. (2007). *ORI Introduction to the responsible conduct of research.* Washington, DC: U.S. Government Printing Office.

Current Federal Regulations

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research became inactive in 1978. Today, the U.S. Department of Health and Human Services' Office of Human Research Protections (OHRP) is the enforcing authority that oversees the protection of human subjects used in research conducted by federally funded agencies and individuals.[28] Federal regulations are incorporated into the requirements of IRB applications and federally funded research. This includes 45 CFR 46 and its subparts, as well as the principles from the Belmont Report.

Subpart A of 45 CFR 46, referred to as the "Common Rule," sets out the basic requirements for privacy and confidentiality for human subjects involved in federally funded programs and research. Subpart A outlines the federal requirements related to IRB membership and operations; review research processes and approval criteria; documentation protocols; informed consent general requirements and protocols; and records in relation to the committee itself and requires assured compliance with federal regulations for IRB review and human subject research. Subparts B through D provide additional protections for pregnant women, fetuses, and neonates involved in research; additional protections for biomedical and behavioral research involving prisoners as subjects; and additional protections for research involving children as subjects.[29] In addition, 42 CFR Part 2 provides additional confidentiality and privacy protections around federally regulated or assisted programs that involve substance use disorder prevention, education, and treatment; these also include exceptions for research purposes.

To ensure federally funded research complies with federal regulations, individuals conducting such research are required training and certification in the protections of human subjects. However, the frequency with which this process should occur is not explicit within the regulations.[30] The Collaborative Institutional Training Initiative (CITI), an online human subject research training collaborative, notes most organizations require refresher courses every three years.[31] Any agency in which staff engages in human subject research also is required to file an "Assurance" of protection for human subjects with OHRP, formalizing their commitment to uphold these protections.[32]

Institutional Review Boards

Another mechanism of oversight for the protection of human subject research are institutional review boards (IRBs). IRBs are charged with overseeing the protection of the rights of human subjects in research.[33] IRBs must review all federally funded human subject research protocols prior to the start of any research (*Figure 2*).[34] However, research that is not funded by a federal agency does not require IRB approval of protocols and processes.

Federal regulations indicate IRBs can:

- Approve, disapprove, or modify research.
- Conduct continuing reviews of research.
- Observe and/or verify changes in research.
- Suspend or terminate approval for research.
- Observe the consent process and research procedures.[35]

IRBs must adhere to federal requirements and are tasked with weighing the following for each study involving human subjects:

- Risks to subjects are minimized and whether risks identified are reasonable in relation to potential benefits and importance of knowledge gained.
- Equity of subject selection.
- Protocols for informed consent are appropriately documented and whether/how informed consent will be sought from the study subject participants.
- Protocols in the research plan provide adequate provision of monitoring data collection and use, ensuring the safety of subjects; and
- Protocols protect the privacy and confidentiality of research subjects are adequate.[36]

IRB member requirements include personally conducting or overseeing research; making sure all staff involved understand rules and regulations governing the research; ensuring fidelity to the research protocols outlined in the IRB-approved proposal; ensuring compliance with IRB requirements for reporting purposes, human subject confidentiality, privacy, and information security; obtaining informed consent; keeping thorough documentation of IRB protocols, processes, informed consent, and research activity; and ensuring any modifications or changes made to the research are first reviewed and approved by the IRB.[37]

Researchers who do not follow IRB requirements and ethical guidelines may face the following consequences.

- Suspension of the research project and/or all of the principal investigator's research projects.
- Suspension and/or termination of all research at an organization.
- Inability to use or publish data and results from the research.
- Inability to receive federal grant funds.
- Increased and additional IRB monitoring and oversight and/or third-party oversight of research.
- Loss of license(s) and/or employment.
- Notification of non-compliance to sponsors, other regulatory agencies, and funding agencies.[38]

Figure 2.
IRB Composition under the Common Rule

- A minimum of five members who are diverse in gender, race, culture, and profession.
- At least one member whose main concern/profession is in a nonscientific area, as well as at least one member whose profession is in a scientific area.
- At least one member who is not affiliated with the organization housing the IRB.
- A member with experience/expertise in all areas of research that may come up for review, including vulnerable populations.
- Members with sensitivity to community attitudes.
- Members that understand organizational commitments and regulations, applicable laws, and standards of professional conduct and practice.
- Members who may have competence in special areas to help in research review that may be beyond IRB member capacity, per discretion of the IRB.

Source: Selwitz, A. S., Epley, N., & Erickson, J. (2018). *Basic Institutional Review Board (IRB) regulations and review process.* Collaborative Institutional Training Initiative (CITI) program.

Freedom of Information Act

The Freedom of Information Act (FOIA) of 1966 allows for more transparency and public inspection of non-sensitive governmental information from federally funded research.[39] However, FOIA also allows several exemptions, including protection of "personal privacy, trade secrets, national security, personnel records, and privileged communications (*Figure 3*)."[40]

The Shelby Amendment (part of FOIA) requires agencies to disclose data collected as part of federally funded research related only to published research findings from the study, or that data which "were used by the federal government in developing an agency action that has the force and effect of law," upon formal request. [41] Exceptions are in place to protect confidentiality and privacy.[42] Further, only data related to federally supported, published research findings are required for disclosure under FOIA.[43] Researchers should remove personally identifiable information prior to disclosure, balancing privacy protections and intellectual property rights with research accountability and transparency.[44]

FOIA disclosure exemptions also include those listed in statutes compiled for law enforcement. They also may apply when release of records and other information could compromise adjudication or law enforcement processes, among others (see *Figure 3*, number 7).[45]

Figure 3.
Nine Exemptions under FOIA

1. Information classified to protect national security.
2. Information purely related to internal personnel rules and agency practices.
3. Information prohibited from disclosure by another federal law.
4. Confidential or privileged trade secrets, commercial, or financial information.
5. Communication between agencies that is privileged, including deliberative process privilege, attorney-work product privilege, and/or attorney-client privilege.
6. Information that would invade another's individual personal privacy if disclosed.
7. Information compiled for law enforcement purposes that could reasonably be expected to interfere with law enforcement proceedings and investigations; privacy, safety, and confidentiality of an individual; and/or impede the rights of an individual.
8. Information regarding supervision of financial institutions.
9. Geological information on wells.

Source: U.S. Department of Justice. (n.d.) *FOIA*. Washington, DC: Author. Retrieved from https://www.foia.gov/faq.html.

Additional U.S. Privacy Protections

Family Educational Rights and Privacy Act

The Family Educational Rights and Privacy Act **(**FERPA) protects the privacy of individuals' education records for schools receiving U.S. Department of Education funds.[46] The Act requires written permission for disclosure of students' educational records from a parent/guardian or eligible student, with certain exceptions.[47] These exceptions include (but are not limited to): disclosure to "school officials" with a "legitimate educational interest" to have the information (which must be disclosed in the school's annual notification of FERPA rights); disclosure to another school a student seeks or intends to enroll; for financial aid application purposes; and/or postsecondary education information disclosure in connection with a health or safety emergency.[48]

Health Insurance Portability and Accountability Act Privacy Rule

The Health Insurance Portability and Accountability Act Privacy Rule (HIPAA) was created with the understanding that the privacy and confidentiality of personal health information must be protected, while simultaneously recognizing researchers have legitimate needs to use, access, and disclose individually identifiable personal health information to conduct vital, potentially life-saving research. This set of federal regulations provides information on when and which protected health information may be used or disclosed by "covered entities" for research purposes.[49] Covered entities include "health plans, health care clearinghouses, and health care providers who electronically transmit any health information in connection with transactions for which the Department of Health and Human Services has adopted standards."[50] Some government agencies, such as health departments, may be considered covered entities or "hybrid entities," if the agency engages in both covered and non-covered functions.[51]

Covered entities may disclose personal health information in the following manner, per the HIPAA Privacy Rule:

1. Through written authorization for release of information from the potential human subjects.[52]
2. Through use or disclosure of deidentified, protected health information for research purposes in accordance with 45 CFR 164.502(d) and 45 CFR 1.64.514(a)-(c) as defined by the HIPAA Privacy Rule.
3. Through securing a waiver of authorization provided and approved by an IRB or Privacy Board (45 CFR 164.512 (i)). [53]

In addition, HIPAA allows a covered entity to use or disclose identifiable protected health information for research purposes without individuals' authorization if the covered entity obtains one of the following from the researcher:

- Documented approval from an IRB or Privacy Board.
- Written or oral description that the use or disclosure of protected health information is for the purposes of research protocol preparation or other preparatory research purposes (e.g. feasibility study).
- Written or oral description that the protected health information for use or disclosure is solely for research of decedents.
- A data use agreement between the researcher and covered entity for use of a limited data set in which specific identifiers are excluded and in compliance with several stipulations regarding use and transmission of the data.[54]

Conclusion

Responsible research plays an important role in new information, growth, and improvement in the body of knowledge in social sciences. There can be many social and individual benefits from research study participation as a human subject. Most frequently, research provides a social benefit or outcome that is socially valuable.[55] For example, this may be increasing knowledge, informing new policies or programs that may benefit society or discovering new treatments. On an individual level, this benefit may be learning something new that may benefit you or receiving treatment that one may otherwise not receive in a clinical setting.

The unfortunate history of research abuses ultimately resulted in comprehensive principles, guidelines, and federal and state regulations to protect human subjects as part of research. This includes consequences for conducting unethical or harmful research, which can result in legal ramifications. Human subject research protections attempt to balance the necessary privacy, confidentiality, and welfare of a research subject, while recognizing the necessity and role that research has in conducting studies ethically and humanely to further knowledge.

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[13] The Nuremberg Code (1947) | The British Medical Journal. (1996). Retrieved August 15, 2018, from https://www.bmj.com/content/313/7070/1448.1
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