

Chapter 1: History and Ethical Principles

Introduction

The first century physician Celsius justified experiments on condemned criminals in Egypt using wording that became a classic defense for hazardous experimentation: "It is not cruel to inflict on a few criminals sufferings which may benefit multitudes of innocent people through all centuries." [\[Brady & Jonsen\]](#).

Both the ethics regarding human subjects research and regulations for such research have changed considerably since Celsius' time. This chapter discusses the evolution of ethical review principles, and how they have influenced research involving human subjects.

By the end of this chapter you will be able to:

Discuss why ethics are necessary when conducting research involving human subjects.

Describe the major historical events that have influenced how research involving human subjects is conducted.

Identify problems with past studies that have violated ethical standards.

**Describe the Belmont Principles.
Discuss the ethical standards for research that guide us today.**

1.1 : Why Are Ethics Necessary

We are concerned with normative ethics, asking questions such as: What ought morality be? How should researchers behave? How should researchers not behave? What character traits should researchers cultivate as virtues? And, what character traits should researchers try to avoid?

There are many advantages to understanding research ethics. Concepts of research ethics:

Provide us with a structure for analysis and decision-making.
Support and remind researchers to protect human subjects.
Provide workable definitions of benefits and risks, along with guidelines for evaluating and balancing the benefits and risks of our studies

1.1.1: Definition of "Benefit"

A benefit is the positive value or advantage of being part of the research study. This value or advantage might be concrete for individual subjects, like a greater chance of having a good therapeutic outcome. Alternatively, it might be more intangible and general. For example, the results from a study could be crucial to understanding the underlying socioeconomic causes of drug addiction.

1.1.2: Definition of "Risk"

Risks generally are evaluated according to the probability and magnitude of any harm that might occur. Will the risk occur in almost all subjects or in only one of 10,000 subjects? We can also quantify risk according to the magnitude of harm. Will the harm consist of some minor itchiness, or will some subjects die? Risks can also be classified according to their type. In medical research we often focus on physical risk. However, risks may also be social, legal, economic or psychological in nature. In addition, risks may apply to the individual subject or may apply to a broader segment of the society.

1.1.3: Balancing Benefits and Risks

Risks to the subject or society must be weighed against potential benefits. The probability of harm relative to the probability of benefit should be determined, as well as the relative magnitude of risks and possible benefits. As an aside, payment for study participation should never be considered a benefit. One of the most difficult things that researchers and IRBs have to do is to determine that the potential benefits of the outcomes of the research outweigh the risks of conducting the research. This is difficult because:

Neither the potential benefits or risks can be known ahead of time.
The risks are assumed by individuals, while the benefits may accrue to society at large rather than to individuals.

1.2 : Historical Events that Have Influenced Human Research

1.2.1: First Documented Human Subject Research

The development of research ethics has evolved over time. Among the first human subject research experiments to be documented were vaccination trials in the 1700's. In these early trials physicians used themselves or their family members as test subjects. For example:

Edward Jenner (1749-1823) first tested smallpox vaccines on his son and on neighborhood children.

Johann Jorg (1779-1856) swallowed 17 drugs in various doses to record their properties.

Louis Pasteur (1822-1895) "agonized over treating humans," even though he was confident of the results obtained through animal trials. He finally did so only when he was convinced the death of the child, the first test subject, "appeared inevitable." [\[Rothman\]](#)

1.2.2: The Era of Modern Science

The era of modern science started in the 1900's and the progress of medicine began to accelerate. Walter Reed's well-known experiments to develop an inoculation for yellow fever were at the forefront of these advances. These experiments, however, unlike earlier experiments with vaccinations, were carefully scrutinized.

Dialog from testimony before the Royal Commission of Vivisection (1908) follows [\[Brady & Jonsen\]](#):

Commission: I understand that in the case of yellow fever the recent experiments have been on man.

Osler: Yes, definitely with the specific consent of these individuals who went into the camp voluntarily.

Commission: We were told by a witness yesterday that, in his opinion, to experiment upon man with possible ill result was immoral. Would that be your view?

Osler: It is always immoral, without a definite, specific statement from the individual himself, with a full knowledge of the circumstances. Under these circumstances, any man, I think is at liberty to submit himself to experiments.

Commission: Given voluntary consent, you think that entirely changes the question of morality or otherwise?

Osler: Entirely.

1.2.3: Nuremberg Code

Society's high regard for the medical profession, however, was not to last. At the end of World War II, 23 Nazi doctors and scientists were put on trial for the murder of concentration camp inmates who were used as research subjects. Of the 23 professionals tried at Nuremberg, 15 were convicted, 7 were condemned to death by hanging, 8 received prison sentences from 10 years to life, and 8

were acquitted. [\[Mitscherlich & Mielke\]](#) Included in the legal judgment and sentences handed down at the culmination of the trial were ten points describing required elements for conducting research with humans. These points became known as the Nuremberg Code.

In summary, the Nuremberg Code includes the following guidance for researchers:

- Informed consent is essential.
- Research should be based on prior animal work.
- The risks should be justified by the anticipated benefits.
- Only qualified scientists must conduct research.
- Physical and mental suffering must be avoided.
- Research in which death or disabling injury is expected should not be conducted.

1.2.4: Effect of the Nuremberg Code

The Code had little impact on researchers in the United States, who thought that the principles in the Code were already implicit in their work and that it was simply a document to condemn the Nazi atrocities and to convict the Nazi doctors. There were a number of problems with the Code itself. For example it did not have the strength of law, it was created post hoc, and it applied to only non-therapeutic human subjects research.

1.2.5: Declaration of Helsinki

In 1964 the [World Medical Association](#) developed a code of research ethics that came to be known as the [Declaration of Helsinki](#). It was a reinterpretation of the Nuremberg Code, with an eye to medical research with therapeutic intent. Subsequently, journal editors required that research be performed in accordance with the Declaration. In principle, this document set the stage for the implementation of the Institutional Review Board (IRB) process. [\[Shamoo & Irving\]](#)

1.2.6: Beecher Article

In 1966 Dr. Henry K. Beecher, an anesthesiologist, wrote an article (Beecher HK. "Ethics and Clinical Research" NEJM June 16, 1966) describing 22 examples of research studies with controversial ethics that had been conducted by reputable researchers and published in major journals. Beecher wrote, "medicine is sound, and most progress is soundly attained;" however, if unethical research is not prohibited it will "do great harm to medicine." Beecher provides estimates of the number of unethical studies and concludes, "unethical or questionably ethical procedures are not uncommon." [\[Beecher\]](#)

Beecher's article played an important role in heightening the awareness of researchers, the public, and the press to the problem of unethical human subjects research. ***"Until this article we assumed that unethical research could only occur in a depraved regime like the Nazis."***- Robert J. Levine, MD (personal communication).

1.3 : Ethical Problems with Past Studies

1.3.1: Ethical Problems

The Beecher article and increased public awareness brought to light problems with ethics in research such as the following:

1. Lack of informed consent
2. Coercion or undue pressure on volunteers (or on a parent to volunteer their child)
3. Use of a vulnerable population
4. Exploitation of a vulnerable population
5. Withholding information
6. Withholding available treatment
7. Withholding information about risks
8. Putting subjects at risk
9. Risks to subjects outweigh benefits
10. Deception
11. Violation of rights

1.3.2: Historic Case Studies

Each of the following exhibited one or more of the ethical problems listed above.

1.3.2.1: Willowbrook Hepatitis Study

In 1956, at an institution for mentally retarded children in Staten Island, New York, a study was initiated to determine the natural history of viral hepatitis and to test the effectiveness of gamma globulin as an agent for inoculating against hepatitis. Children were deliberately infected with a mild form of hepatitis.

The investigators defended the study by stating that most new children would become infected with hepatitis within their first 6-12 months at the institution. Although permission was obtained from parents, the parents were not fully informed of the possible hazards involved in the study. There is evidence that the parents were led to believe that the child would not be enrolled at the school unless the parents signed the consent form.

Ethical problems: exploitation of a vulnerable group of subjects, withholding information about risks, coercion or undue pressure on parents to volunteer their children. [[Munson](#)]

1.3.2.2: Jewish Chronic Disease Study

In 1963 live cancer cells were injected into senile patients without their knowledge as part of a study of immunity to cancer. Since the investigators believed that the cells would be rejected, the researchers did not inform the patients or seek consent because they did not want to frighten them.

Ethical problems: lack of informed consent, use of a vulnerable group of subjects. [[Levine](#)]

1.3.2.3: San Antonio Contraception Study

In San Antonio, Texas, a number of Mexican-American women participated in a 1971 study to determine side effects of an oral contraceptive. The women came to a clinic seeking contraceptives. Unbeknownst to them, the study was designed so that half the women would receive oral contraceptives for the first half of the study, then switched to placebo. The women initially receiving placebo were placed on the oral contraceptive for the second half of the study. 10 of the 76 subjects became pregnant while using placebo.

Ethical problems: lack of informed consent, use of a vulnerable group of subjects, risks to subjects outweighed benefits. [[Levine](#)]

1.3.2.4: Tea Room Trade Study

The study planned first to obtain information about homosexual practices in public restrooms and then to conduct further investigation on the men who took part in the acts. The researcher went undercover and gained the confidence of the men by acting as a "look out." The researcher identified 100 active subjects by tracing their car license numbers. A year after he completed the initial study of direct observation of homosexual acts the researcher distributed a "social health survey" throughout the communities where he knew the subjects lived.

Ethical problems: use of a vulnerable population, reinforced image that social scientists use deception casually in research, lack of informed consent. [[Warwick](#)]

1.3.2.5: Obedience to Authority Study (Milgram Study)

The purpose of this study was to determine response to authority in normal humans. The researchers told recruited volunteers that the purpose was to study learning and memory. Each subject was told to teach a "student" and to

punish the students' errors by administering increasing levels of electric shocks. The "student" was a confederate of the researcher who pretended to be a poor learner and mimicked pain and even unconsciousness as the subject increased the levels of electric shock. 63% of the subjects administered lethal shocks; some even after the "student" claimed to have heart disease. Some of the subjects, after being "debriefed" from the study experienced serious emotional crises.

Ethical Problems: deception, unanticipated psychological harms.

1.3.2.6: The Public Health Service Syphilis Study (1932-1971)

Initiated by the Public Health Service, this study was designed to document the natural history of syphilis in African-American men.

At the time the study began there was no known treatment for syphilis. Hundreds of men with syphilis and hundreds of men without syphilis (serving as controls) were enrolled into the study. The men were recruited without truly informed consent. They were deliberately misinformed about the need for some of the procedures. For example, spinal taps were described as necessary and special "free treatment."

Even after penicillin was found to be a safe and effective treatment for syphilis in the 1940's, the men were denied antibiotics. The study continued to track these men until 1972 when the first public accounts of the study appeared in the national press. The study resulted in 28 deaths, 100 cases of disability, and 19 cases of congenital syphilis. [\[Levine\]](#)

Ethical problems: lack of informed consent, deception, withholding information, withholding available treatment, putting men and their families at risk, exploitation of a vulnerable group of subjects who would not benefit from participation.

1.4 : The Belmont Principles

1.4.1: Research Ethics since the 1970s

The Public Health Service (PHS) Syphilis Study is among the most influential in shaping public perceptions of research involving human subjects. After the press "blew the whistle" on the PHS Syphilis Study, Congress formed an Ad Hoc Panel. The Panel determined that the PHS Syphilis Study should be stopped immediately and that oversight of human research was inadequate. The Panel recommended that federal regulations be designed and implemented to protect human research subjects in the future. Subsequently, federal regulations were enacted including the National Research Act, 45 Code of Federal Regulations 46, and 21 Code of Federal Regulations 50.

1.4.2: The National Commission

In 1974 Congress authorized the formation of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, known to most people in research ethics as The National Commission. Congress charged the National Commission to identify the basic ethical principles that underlie the conduct of human research--to look at the writings and discussion that had taken place up to this time and to ask, "What are the basic ethical principles that people are using to judge the ethics of human subject research?"

Congress also asked the National Commission to develop guidelines to assure that human research is conducted in accordance with those principles.

1.4.3: The Belmont Report

The National Commission met and in 1979 published the [Belmont Report](#). The *Belmont Report* is "required reading" for everyone involved in human subject research.

The *Belmont Report* identifies three basic ethical principles that underlie all human subject research. These principles are commonly called the Belmont Principles. The Belmont Principles are respect for persons, beneficence, and justice.

1.4.4: The Belmont Principles

1.4.4.1: Respect for Persons

This principle is found in the writings of philosopher Immanuel Kant. It requires us to treat individuals as autonomous human beings and not to use people as a means to an end. We must allow people to choose for themselves and provide extra protection to those with limited autonomy.

Elements of autonomy include:

Mental capacity, the ability to understand and process information.
Voluntariness, freedom from the control or influence of others.

Therefore, subjects have full autonomy when they have the capacity to understand and process information, and the freedom to volunteer for research without coercion or undue influence from others.

Rules derived from the principle of respect for persons include:

The requirement to obtain informed consent.
The requirement to respect the privacy of research subjects.

1.4.4.2: Beneficence

This principle reminds us to minimize harms and maximize benefits. Derived rules include:

The requirement to use the best possible research design to maximize benefits and minimize harms.

The requirements to make sure the researchers are able to perform the procedures and handle the risks.

The prohibition of research that is without a favorable risk-benefit ratio.

1.4.4.3: Justice

The principle of justice requires us to treat people fairly and to design research so that its burdens and benefits are shared equitably. Derived rules include:

The requirement to select subjects equitably.

The requirement to avoid exploitation of vulnerable populations or populations of convenience.

1.4.5: Balancing the Three Principles

It was the Commission's intention that each of the three principles should have equal moral force. This means that in some situations, the three principles might be in conflict with one another. For example, we might derive from the principle of respect for persons that we should limit the involvement of children in research because children are unable to choose for themselves. But, we might derive from the principle of justice that we must involve children in studies so that children will have the opportunity to benefit from the research. The *Belmont Report* says that one principle does not always outweigh another. Rather, we are required to consider each case separately and on its own merits in light of all three principles.

1.5 : Ethical Standards for Research that Guide Us Today

In the last several years reports of unethical studies including gene transfer, cancer, and psychiatric research have heightened the public awareness of these issues even further. Two recent examples follow:

-Death of a Normal Volunteer

On March 31, 1996, a 19-year-old Asian American student at the University of Rochester responded to an advertisement for study subjects to undergo bronchoscopy for the harvest of alveolar macrophages. The bronchoscopy was difficult and required numerous doses of topical lidocaine. The investigators

repeatedly asked the subject if she wanted to continue and the subject nodded her head "yes". The study was completed, but the subject returned to the hospital in cardiac arrest from an overdose of lidocaine and died April 2, 1996. An investigation into this death revealed that the protocol did not limit lidocaine doses, that the doses were not documented, that the subject was not observed after the bronchoscopy, and that the concentrations of lidocaine were increased without IRB approval.

-Death on Gene Therapy Trial

In the fall of 1999, eighteen-year-old Jesse Gelsinger died as a result of his participation in a gene transfer trial. Jesse had a rare metabolic disorder, ornithine transcarbamylase deficiency syndrome (OTC) that was being controlled by medication and diet. Researchers were testing an innovative technique using adenovirus gene transfer. Shortly after treatment Jesse Gelsinger experienced multiple organ failure and subsequently died. This case catapulted research with human subjects into the national media. Serious concerns related to conflict of interest, data safety monitoring, and informed consent have made the Gelsinger case a contemporary illustration of continued doubts about the ethical integrity of research with human subjects. This case has instigated deliberations on all these controversial topics at the national level. The outcome of the discussions has yet to be determined.

1.5.1: Applying the Belmont Principles

The need for protecting human subjects through research ethics and regulations is as prevalent now as ever. Applying the Belmont principles to our studies is an important start:

From the **principle of respect for persons** we need to conduct initial and continuing informed consent. We need to evaluate whether the research allows subjects to withdraw from the research and maintains the welfare of each subject.

From the **principle of beneficence** we need to evaluate the social and scientific value of the research, the scientific validity of the research, and determine whether the research has a favorable risk benefit ratio.

From the **principle of justice** we need to evaluate whether there is fair subject selection. We also need to evaluate the inclusion and exclusion criteria and the methods of recruitment.

1.5.2: Applying Research Ethics

Additional considerations in research ethics include the following:

1.5.2.1: Principal Investigator's (PI's) Relationship with Staff

A responsible PI will:

Obtain team management skills.

Encourage questions from colleagues and staff.

Listen to the concerns of the research staff, as they may be the first to point out problems with the protocol and with compliance.

Build consensus with the research team.

Eliminate intimidation by those in supervisory positions.

Authority relationships are not limited to the principal investigator and the staff, but can also include the authority of the sponsor over the principal investigator, the authority of the principal investigator over the subject, and the authority of the protocol over the principal investigator.

1.5.2.2: Investigator-Subject Relationship

The investigator must place the subject's rights, welfare, and safety above all other personal and scientific concerns. The relationship between researcher and subject is similar to a physician-patient relationship, but different in the following ways:

-Informed consent is required for participation in research.

Example: Let us suppose that a patient insists that she does not want to hear about the risks, benefits, and alternatives of a proposed medical procedure. She insists that the physician decide for her. Many would say that it is ethical for the physician to go ahead with the treatment, provided that he/she is convinced that it is in the best interest of the patient.

In research the issue is more complex and the relationship more formal. If a potential research subject is given a consent form, and the subject does not want to read the document and simply asks, "Where do I sign?" the investigator must ethically insist that the subject listen to the investigator's description of the study and other important information. The Investigator must insist that the potential subject read and understand the consent document. If the subject refuses to read the consent or hear a full disclosure of the information about the research, then the investigator has the ethical obligation to prohibit enrollment of the subject.

-Withdrawal from a study is at the discretion of the subject.

Example: A healthy research subject enrolls in a pharmacokinetic study of a drug that is known to cause anxiety and feelings of distrust. After receiving two doses, the subject declares he no longer trusts the researchers and says he will leave. The investigator says, "It's the drug talking" and tries to continue the procedure.

An ethical researcher will permit subjects to withdraw for whatever reason or for no reason. Of course, a researcher must do what is needed for subject safety; in the example above, the investigator should ensure the subject's emotional equilibrium returns to normal.

-Investigators should be sensitive to power relationships.

Example: It is common in basic science laboratories to obtain blood from normal volunteers, usually staff in the research lab. Some blood donors have difficult veins and may need to be stuck several times to obtain blood. Despite the increased pain of multiple sticks, staff members in an investigator's lab may feel obliged to say, "Stick me. I don't care. I don't mind needles." Responsible investigators should recognize the problem and excuse such a person from the study. The investigator should say something to the effect that, "You are experiencing more harm than the average subject. I will find someone else to enter the study who will not experience the same anxiety and harm."

-The investigator has a moral fiduciary relationship with the subject.

Example: There are conflicts of interest that are so great that even the moral investigator will have a difficult time making the right decision. If doing what is right for the subject means losing \$10 million, many of us could be susceptible to making the wrong decision. It is up to the IRB to detect and minimize these conflicts of interests. However, it is also up to the investigator to avoid entering into these untenable conflicts.

1.5.3: Research Ethics and Regulations

Federal regulations are derived from all of these ethical concerns. Federal regulations provide three basic protections to human subjects involved in research:

Institutional assurances.

Review by an Institutional Review Board.

Informed consent. – Chapter 3 of this module will review the Informed Consent process in detail.

1.5.3.1: Institutional Assurances

Institutional assurances are a mechanism to apply federal regulations to all human subject research. When institutions sign federal assurances, they may also elect to apply the Health and Human Services regulations and terms of the assurance to all research of the institution, regardless of the source of funding.

1.5.3.2: Review by an Institutional Review Board

Review by the Institutional Review Board is the glue that holds the evaluation process together. IRB review (described in detail in Chapter 2) is guided by the ethical principles described in the Belmont Report and asks the following questions when evaluating a study:

-Respect for persons

Does the consent process maximize autonomy?
Does the protocol maximize autonomy?
What additional protections have been put in place for vulnerable populations?
Does this study maximally protect subject privacy and confidentiality?

-Beneficence

Is the research design adequate? Can it be improved?
What are the risks? Have they been minimized? Is the subject informed?
What are the benefits? Have they been maximized? Is the subject informed?

-Justice

Does recruitment for the study target the population that will benefit from the research?
Does the recruitment unfairly target a population?
Are the inclusion/exclusion criteria fair?

Ethical principles and federal regulation provide a framework for IRBs to evaluate research involving human subjects. However each research study is unique and thus a comprehensive review may be a complicated process.

Credits

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Chapter 2: Defining Research with Human Subjects

Introduction

It is a critical task to make the distinction between activities that meet the definition of research with human subjects and those that do not. If a project doesn't meet the definition, it will not need review by an Institutional Review Board (IRB). The federal regulations provide basic definitions of "research" and of "human subjects." (It should be noted that reasonable people can and do disagree about how to interpret and apply the definitions.) Sponsors may refer to their agreements with investigators as something other than research, such as an "evaluation contract." However, the federal definition of research takes precedence.

2.1: Defining "Research"

2.1.1: Definition

According to the regulations, research is "a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The following three sections will consider particular words and phrases in the definition.

2.1.2: "Systematic investigation"

In the social and behavioral sciences, much research fits within the traditional understanding of scientific methodology. However, the application of the term "systematic" depends largely upon discipline-specific methodology. A systematic inquiry in psychology might involve observing the interactions between dependent and independent variables. On the other hand, when ethnographers study communities, they may not have *a priori* hypotheses, but their observations and interviews are informed by constructs, such as the function of communities, and are thus systematic in terms of their discipline. An ethnographer who hangs out in a tribal bar is probably not studying how drinks are made, but perhaps how identities are articulated in the context of a dominant culture.

2.1.3: "Including research development, testing, and evaluation"

Pilot studies, feasibility studies, and other preliminary studies clearly fall under the definition of research. Both of the following preliminary components of a study constitute research with human subjects:

A focus group of Latino immigrants helping investigators develop a questionnaire with regard to the transfer of sexually transmitted disease between immigrant-receiving and immigrant-sending communities.

Community pilot testing of the questionnaire prior to the administration of the questionnaire and analysis of the results.

2.1.4: “Designed to develop or contribute to generalizable knowledge”

To generalize is to derive general conclusions from particulars, and is a goal of most basic research. Even research about the most narrowly defined topic, such as an individual case study or the study of an isolated community, may be intended to contribute to some body of knowledge such as the function of culture, the expression of gender, or the political views of marginalized community members.

Some investigators in the social and behavioral sciences and humanities contend that the regulations were designed only to govern biomedical research. They then, reasonably, assume that “generalizable knowledge” is only that which is hypothesis driven, quantitative, and replicable. While it is true that scandals in biomedical research drove the development of the current regulations, the regulations were designed to cover all research with human subjects. The regulations specifically refer to interviews, oral history, focus groups, and other qualitative methodologies. Therefore, the concept of “generalizable knowledge” has to be broadened. (The development of drugs, biologics, and medical devices are governed by a separate set of regulations developed by the Food and Drug Administration.)

An essential consideration is whether it is the intention of the investigator to contribute to generalizable knowledge. Some activities that involve interactions with humans and data gathering may not fit the definition of research with human subjects, since they are designed to accomplish something else, such as in-house quality improvement. For example, a survey of college students about their university’s counseling services may be designed strictly to improve the service delivery for students on that campus, and thus not involve research. (However, should the surveyors believe that the results may be generalizable, they should request IRB review before they initiate the survey.)

Publication of results is sometimes used as a measure of whether research is generalizable, but this is too narrow a measure for two reasons. First, not every study will produce results worthy of publication. Second, there are multiple ways in which results can be made available to others without being published in a peer-reviewed journal. Results may be presented at a conference or made the subject of a seminar. They may be shared with colleagues through the Internet, appear in a dissertation, or provided to Board members in a project report.

2.2: Defining “Human Subject”

2.2.1: Definition

According to the regulations, A human subject is a “living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual.

or

2. Identifiable private information.”

The following four sections will consider key words and phrases in the definition

2.2.2: “A living individual about whom”

Most research in the social and behavioral sciences involves gathering information **about** individuals. But that is not always the case.

Consider the following scenario. An investigator is developing computer voice recognition software. He asks students to come to the lab and record a series of predetermined words and phrases. The project is research intended to contribute to generalizable knowledge, and it includes an interaction with individuals in a laboratory setting. However, the definition of a human subject begins, “a living individual about whom an investigator collects data...” The research is not **about** the students; they are not the unit of measure. No data about them will be collected. They are simply providing sounds to help the investigator assess the functions of the computer.

2.2.3: “Interventions”

Interventions include physical procedures through which data are gathered, such as measuring brain function to supplement paper and pencil inquiries into the development of language. They also include manipulation of the subject or the subject’s environment, for example, studies investigating the impact of environmental factors on cognition or memory.

2.2.4: “Interactions”

Interactions include communication or interpersonal contact between the subject and the investigator. Communication does not have to be face to face, and may even exist entirely on paper or in electronic realms. Participant observation, such as occurs in some ethnography, is a variant of interaction, often including both formal and informal interviews in addition to observation.

2.2.5: “Identifiable private information”

As defined in the regulations, “private information includes:

1. Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.

and

2. Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).”

Private information must be individually identifiable in order for the collection of the information to constitute research with human subjects. Subjects may be indirectly identified through combinations of data fields, for example, the only Korean faculty member with tenure.

The following two sections will expand on the definition of private information.

2.2.5.1: Part 1 of the definition

It is important to keep in mind that whether a setting is public is, by federal definition, determined in large part by the potential subjects’ expectations of privacy, rather than any absolute distinctions between public and private spaces. For example, one might expect that certain behavior, even if conducted in public spaces, is in fact private, such as a conversation in a public park. It is reasonable to assume that one might expect not to be taped while dining with a date at a restaurant.

If investigators wish to obtain information in a context in which subjects would have a reasonable expectation of privacy, the investigator must use covert observation (concealed recording devices and videotaping or use of a one-way mirror) or assume a role in the setting or group being studied. Such studies raise significant concerns about violation of privacy and require additional protections and safeguards for subjects. Observational studies in quasi-public places, for example, hospital emergency rooms or state mental hospital wards, may also raise such concerns.

If you are not sure whether a study meets the definition of research with human subjects, please consult your IRB.

2.2.5.2: Part 2 of the definition

Individuals provide personal information, with the expectation that it not be made public, in a variety of settings: at work, at school or college, when receiving health care, or as a member of an organization.

Some of this information is protected by law and cannot be released with identifiers without express written permission. For example, school records are protected by the Family Education Rights and Privacy Act (FERPA).

Data files including identifiable private information are compiled and maintained by both public and private institutions. So an investigator studying the relationship between private gun ownership and crime could consult the National Crime Victimization Survey that includes data collected by the Census Bureau on behalf of the Department of Justice, a public institution. The investigator could also use data from the National Opinion Center at the University of Chicago, a private institution.

Usually, the owners of such data sets place restrictions on their use and will release identifiable data only to investigators with IRB approved data protection plans. For example, the Department of Justice issues public reports based on the National Crime Victimization Survey and also makes limited data sets publicly available. However, data from the survey that contains geographical identifiers are restricted.

Under some circumstances, the use of pre-existing data does not constitute research with human subjects. If the source of the data does not maintain identifying information (and does not have any method for identifying subjects, such as a key that links a subject to their data) and if subjects cannot be identified indirectly, the research does not meet the definition of “research with human subjects.” The analysis of the data does not involve interaction or interventions with living human beings. Private identifiable information is neither being collected by the investigators nor received from an outside source.

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Chapter 3: The Regulations and The Social and Behavioral Sciences

Introduction

How can research in pediatric oncology and political science be governed by the same set of regulations? It is a legitimate question with at least three answers. The first answer is that they do indeed involve very different kinds of inquiry and carry significantly different risks. The second answer is that all research ought to be guided by the same ethical principles. For example, just as pediatric oncologists would strive to minimize harm and discomfort to their young patients, so would political scientists strive to minimize the potential for a breach of confidentiality that might cause harm to their subjects. The third answer is that the federal regulations include a number of provisions that provide flexibility for social and behavioral scientists whose research carries negligible or minimal risk.

Flexibility is provided in two primary ways. One is that options for review are provided for research that is inherently free of risk (a inoffensive survey that doesn't collect identifiers) or one with no more than minimal risk. These review options will be discussed in this chapter. The second primary area of flexibility is the informed consent process, as discussed in the chapter 5, Informed Consent.

3.1: Federal Regulations for Protecting Research Subjects

Research with human subjects is governed by federal, state, and local laws, as well as by institutional policy. This chapter will only cover the federal regulations which are designed to provide minimum standards for protecting research subjects.

3.1.1: Overview

The federal regulations are often referred to as the Common Rule. The regulations were first written by the Department of Health and Human Services (DHHS). Subsequently, most departments that fund research in the social and behavioral sciences, including the National Science Foundation and the Department of Education, adopted the regulations, thus the designation "Common Rule."

The DHHS regulations are sometimes referred to as 45 CFR 46, Subpart A, a label that identifies their location in the Code of Federal Regulations. You will probably see 45 CFR 46 quoted in your institution's policies and resource materials.

3.1.2: Additional Subparts to the DHHS Regulations

Three subparts have been added to the basic provisions of the DHHS regulations. Each provides additional safeguards for populations identified as vulnerable.

1. Subpart B, Pregnant women, fetuses, and neonates.
2. Subpart C, Prisoners.
3. Subpart D, Children.

With regard to flexibility, the additional protections for children include the same options for the informed consent process as Subpart A. However, review options are limited when the subjects are children. The additional protections for prisoners are designed to curtail the kinds of research that can take place in a prison setting, and may require consultation with the Secretary of the Department of Health and Human Services. The protections for pregnant women, fetuses, and neonates focus on medical research. There is no additional risk to pregnant women in survey about how people form political opinions.

The Common Rule, Subpart A of the DHHS regulations, does not include the subparts. Some federal agencies that have adopted Subpart A have not adopted the additional subparts. For example, the Department of Education has adopted the additional protections for children; the National Science Foundation has not.

3.1.3: Applying the Regulations

Most institutions decide to apply the Common Rule to all research with human subjects, regardless of the source of funding. This position is based on the premise that the regulations reflect ethical principles common to the entire research enterprise and that all research subjects should be provided the same protections, regardless of the source of financial support for the research. Most, but not all, institutions also choose to apply the additional subparts to all research regardless of the source of funding. Some institutions choose to apply the subparts only when required by a federal sponsor.

3.1.4: Assurance with the Office of Human Research Protections

Every institution conducting research with federal support from the DHHS is required to enter into an agreement called an “assurance.” Assurances are negotiated with the DHHS Office for Human Research Protections (OHRP). Other federal agencies that have adopted the Common Rule agree to accept an assurance issued by DHHS. An assurance identifies the basic regulations the institution will follow (in the United States, the Common Rule). It also states how broadly the institution will apply the Common Rule and the additional protections for vulnerable populations as described in Subparts B, C, and D of the DHHS

regulations. The assurance also registers the institution's Institutional Review Boards (IRBs).

3.2: Content of the Regulations: An Overview

The regulations state:

1. What research must be reviewed.
2. Who must review it (the full IRB, a member of the IRB, or an institutional official.)
3. What questions should be addressed in the review process.
4. What kinds of review need to take place during the life of a project.

It should be noted that some review process are described in detail in the regulations and some are left to the discretion of the institution. For example, the criteria for initial review are described in detail, but the criteria for review of amendments and reports of unanticipated events are not. Some review criteria are expanded upon, such as informed consent, and others, such as just subject selection, are not. Similarly, two types of review processes, expedited and full review, are described in detail, but the process for determining if research is eligible for exemption is not. Therefore, it is always important to check your institution's policies.

3.2.1: What Must Be Reviewed

The first step in deciding whether a project needs review is to determine whether it meets the definition of research with human subjects. The second step is to determine whether the regulations require that the research be reviewed.

3.2.2: Research Eligible for Exemption

Of significant interest to social and behavioral scientists is the fact that there are activities that **do** meet the definition of research with human subjects but are **not** covered by the provisions of the Common Rule. Thus they do not require review as described in the Rule. They are, however, subject to the ethical principles adopted by the institution. For example, the Belmont Report requires a consent process for **all** research.

While these studies do not require review in accordance with the Common Rule, some procedure is necessary to make the determination that they are eligible for exemption. Institutional procedures vary, but the common element is that the institution must make the determination, not the investigator.

Research may be eligible for exemption if **all** the activities associated with the research fall into one of six categories. Of the six categories, three are frequently used by social and behavioral scientists. They are:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices

2. Research involving survey procedures, interview procedures, or observation of public behavior providing that any disclosure of identifiable information outside the research setting would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

NOTE: If Subpart D applies, either by sponsor requirement or institutional choice, interviews with children and participant observation with children cannot be exempt.

3. Research involving the collection or study of existing data (collected prior to the research for purposes other than the research) if the data is publicly available or recorded by the investigator in such a manner that the subjects cannot be identified

A complete list of eligible activities is provide at [45 CFR 46.101](#).

3.3: Who Must Review Research with Human Subjects

As proscribed in the regulations and implemented by institutional policy, there are three possibilities. Research may be reviewed by a convened Institutional Review Board (full review), one or more IRB members (expedited review), or by an individual designated by the institution who may not be an IRB member (exemption approvals). The criteria for determining who conducts the review includes:

- Level of risk.
- Research activity.
- Vulnerability of subjects.
- Institution-specific criteria.

3.3.1: Expedited or Full Review?

To be eligible for expedited review research must meet two criteria:

1. Pose no more than minimal risk to subjects.

"No more than minimal risk" means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

2. Consist of one or more [research activities specified in the regulations](#) .

Eligible activities are similar to those for exempt research (some surveys, interviews, and data analysis) with the addition of some minor and non-invasive medical procedures, such as blood pressure readings, occasionally used by social and behavioral sciences. The preamble to the list of activities notes that if the primary risk to subjects is a breach of confidentiality and that risk can be managed to no more than minimal, the research may be reviewed with through expedited process.

Subject population and institutional policy may require review by a convened IRB even for a study with no more than minimal risk, such as a study of decisionally-impaired individuals. If research involves more than minimal risk and/or does not fall into one of the categories of activity eligible for expedited review, it must be reviewed by a convened IRB. This review involves consideration by a larger, more diverse group, thus bringing more perspectives and more experience to the review.

3.3.2: Description of an Institutional Review Board

An Institutional Review Board is a review committee established to help protect the rights and welfare of human research subjects. Although federal regulations use the term IRB, institutions may choose a different name for the committee.

3.3.2.1: Membership

The minimum size and required composition of an IRB is spelled out in detail in the regulations. Its membership is expected to be sensitive to community attitudes; have knowledge and experience with vulnerable populations; and to understand its institution's commitments and regulations, applicable state and local laws, and standards of professional conduct.

The most important requirement is that an IRB must have the expertise and professional competence to evaluate research. One or more members must have familiarity with the discipline and methodology under consideration. If not, the IRB must seek that expertise through consultation. For example, if an IRB is to review research on sensitive topics using web-based surveys, it must have expertise about security issues in the Internet environment or seek outside consultation.

3.3.2.2: Authority of the Institutional Review Board

Federal regulations stipulate that an IRB can:

- Approve research.
- Disapprove research.
- Modify research.
- Conduct continuing reviews.
- Observe/verify changes.
- Suspend or terminate approval.
- Observe the consent process and the research procedures.

The regulations also require that IRBs develop procedures for handling noncompliance.

3.3.2.3: Other Institutional Reviews

Research approved by an IRB may be subject to further review and approval or disapproval by officials of the institution (for example, department heads, deans, research directors). However, those officials may not approve the research if it has not been approved by an IRB. If an IRB has disapproved the research, the institution cannot override that determination.

3.3.3: Review Criteria for Expedited and Full Review

IRB members conducting an expedited review, or the convened IRB conducting a full review, must ask the following questions:

1. Have the risks to subjects been minimized using procedures that are consistent with sound research design?
2. Are the risks reasonable in relation to anticipated benefits?
3. Is the selection of subjects equitable?
4. Are adequate procedures in place to ensure privacy and confidentiality?
5. Is there a plan to monitor the data and safety of the subjects?
6. Has informed consent been sought and appropriately documented? Do proposed waivers meet the criteria for approval?
7. Are safeguards in place to protect vulnerable populations?

3.3.4: Comparison of Expedited and Full Review

Review procedures for expedited review and full review are similar in several ways:

The review criteria are the same.

Both types of review are documented communication processes between investigators and reviewers.

Expediting reviewers and the full IRB can request modifications to submissions and can approve protocols, continuing reviews, and amendments to approved protocols.

Expediting reviewers and the IRB will specify when a protocol must be reviewed again. By regulation it must be within twelve months, but shorter review periods may be required.

A key difference between the two processes is that expedited reviewers cannot disapprove a protocol. They must refer protocols they cannot approve to the full IRB. All IRB members must be advised about protocols, continuing reviews, and amendments approved through expedited review procedures. Any member of the IRB may request that such approvals be reconsidered by the full IRB.

3.4: Reviews throughout the Life of a Project

Once a protocol has received initial approval it must be reviewed again, according to procedures described in the Common Rule, within twelve months of its approval date. This review may be conducted through the expedited review process or at an IRB meeting. In addition, changes to an approved protocol must be approved and reports of unanticipated problems must be reviewed.

3.4.1: Continuing Review

Federal regulations permit expedited review procedures to be used for continuing review if the initial review was expedited and no new risks have been identified. It may also be used when the initial review was conducted by a full IRB under some circumstances, for example, where no subjects have been enrolled and no additional risks have been identified, or where the remaining research activities are limited to data analysis.

The IRB or the expediting reviewer(s) must determine that all the requirements for initial review continue to be satisfied. The Common Rule also requires that continuing review cover specific information, including the number of subjects

accrued, a summary of any new relevant information, and description of any unanticipated problems. Follow the link to view the latest Guidance from the OHRP on [Continuing Review](#).

-Continuing Review and Exempt Research

Continuing review is not a regulatory requirement for exempt research, although some institutions do require it. Proposed amendments must be reviewed in some manner to ensure that the revised research still meets the criteria for exemption.

3.4.2: Amendments

Changes to approved protocols must be approved prior to their implementation. The regulations state that expedited review procedures may be used to approve "minor changes in previously approved research during the period (of one year or less) for which approval is authorized." Consult with your IRB about your institution's policies and procedures regarding these reviews.

3.4.3: Reports of unanticipated risks or harms

Procedures for reporting and reviewing unanticipated risks or harms must be developed by institutions. Check with your IRB.

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Chapter 4: Assessing Risk in Social and Behavioral Sciences

Introduction

One of the most important and challenging tasks that investigators face is identifying and evaluating risks associated with participation in research. Unlike biomedical research studies or clinical trials, in which the sources of risk may be more readily identifiable and quantifiable, risks associated with participation in social and behavioral science research are often more elusive and less predictable. However, this does not mean that these risks are any less serious or less real. Consider the damage that could result from an inadvertent disclosure of sensitive personal information, such as sexual orientation or a diagnosis of mental illness. Discrimination resulting from such disclosures could have serious consequences.

Risks traditionally associated with social and behavioral sciences can be present in all research, even biomedical research. Every interaction in a research context is a communication of some sort, and communications can go awry. For example, notification by mail to set up a follow-up appointment for a participant in a research study may result in an inadvertent breach of confidentiality.

4.1: Risks Associated with Participation in Social and Behavioral Sciences Research

4.1.1: Risk in social and behavioral sciences generally fall in three categories

- Invasion of privacy.
- Breach of confidentiality.
- Study procedures.

In rare circumstances, the risks associated with social and behavioral sciences may be physical in nature and not trivial. Physical harassment or arrest was identified as a risk in a study of the black market economy in Cuba. Those who study victims of domestic violence need to consider that their subjects may become the victims of retaliatory violence.

Groups and communities are also subject to harm if research results in, for example, stigmatizing a community. Research causing group harm includes the many studies comparing the average IQ of "racial" groups or the prevalence of HIV infected individuals in communities.

4.1.2: Invasion of Privacy

Invasions of privacy can occur if personal information is accessed or collected without the subjects' knowledge or consent. Invasions of privacy can occur if a subject's participation in a study is revealed without the subject's knowledge. For example, an investigator communicating via e-mail with subjects in a study about recovering from sexual assault needs to be aware that e-mail is not private and can be read by family members and even employers.

4.1.3: Breach of Confidentiality

Perhaps the primary source of risk in the social and behavioral sciences is that information obtained by researchers could harm subjects if disclosed outside the research setting. Confidentiality can be compromised through an unauthorized release of data, which could have a negative impact on the subjects' psychological, social, or economic status. For example:

An unintended disclosure of subject's HIV status could result in the subject's loss of employment or health insurance coverage.

Public revelations of data collected about sexual preference could result in a loss of social status or discrimination in housing or employment.

Workers asked to reveal their attitudes about the effectiveness of their managers could lose their jobs or be denied promotions if the information is not adequately protected.

Information about illegal activities or status (drug use or immigrant status) can have serious legal consequences for subjects.

4.1.4: Study procedures

In some cases, simply participating in the research can cause social or psychological harm. For example, research may induce psychological distress in a participant responding to questions regarding a sensitive topic or past traumatic event.

4.2: Assessing Risk

4.2.1: Probability and Magnitude of Harm.

When assessing risk associated with participation in a research study, there are two distinct elements of risk that need to be considered. One is the probability of harm – the likelihood that a specific harm might occur. Not all possible harms are equally probable, and this fact should be taken into consideration when assessing risk. The second element of risk is the magnitude of such harm.

Sometimes there is great disparity between the probability and the magnitude of harm in a study. Consider the following scenario: A researcher wants to do a web-based survey of college students to elicit information about their sexual behavior and drug use. Identifiers will not be collected; however, the data is vulnerable in transit from an individual's PC to the web server hosting the survey, much in the same way credit card information is vulnerable during transit. The probability that the data could be "snatched" in transit and identified through the IP address of the sending computer is low, but it could be done. The magnitude of the possible harm is very high given the sensitivity of the information. (The risk could be managed by encrypting the data at its source which is a relatively easy procedure.)

It may not be possible to identify clearly the probability of risks in a study. For example, existing literature indicates that asking college students to write about the worst thing that ever happened to them is unlikely to cause serious distress - but it might, and there is no way to know how much. Thus, researchers need to be prepared to respond to distress, even though they may never need to use their response procedures.

4.2.2: Situation and Time

Risks in research participation are specific to time, situation, and culture. Thus, what may be a socially sensitive issue or topic at one time or place may not be so at another time or place. For example, asking women if they have had abortions would carry very different risks in cultures where abortion is a routine medical practice, a country where it is illegal, and a country in which it is legal but the issue is fraught with religious and political controversy.

4.2.3: Subject Population.

Risks will differ according to the subject population, too. Consider this case: A study on the efficacy of a behavioral intervention for smoking cessation involves both adults and teenagers. Purchasing tobacco products is generally illegal for persons under 18 years of age. For adults, however, it is a health hazard, but not an illegal activity. Thus, any assessment of the risk for teenagers will have to consider that the research focuses on an illegal activity.

Similarly, a survey about sexually transmitted diseases would carry different risks for middle class suburban men, Catholic clergy, and gang members (who in one study claimed to have STD's when they did not).

4.2.4: Assessing Risk Objectively.

4.2.4.1: Investigators

People, including researchers, tend to underestimate risks involved in activities with which they are familiar and to overestimate the benefit of things that are important to them. Thus, an independent assessment of risk is critical. One

function of Institutional Review Boards is to provide this independent assessment.

4.2.4.2: Potential Subjects

Research indicates that when potential outcomes are severe, people tend to over estimate their probability, regardless of the true probability. And when potential outcomes are less severe, such as embarrassment, people tend to underestimate their probability. A good consent process will address these tendencies.

4.3 Balancing Risks and Potential Benefits

Federal regulations, based on the ethical principle of beneficence, require that risks associated with research be reasonable in relation to the anticipated benefits.

A great deal of research in the social and behavioral sciences offers little potential for direct benefits to the subjects themselves. The benefits of the research often lie in the importance of the knowledge to be gained, the contributions it makes to science, or the contributions to society in general. There might also be cases in which a specific community, rather than the individual subjects, benefits from the research. On the other hand, most research in the social and behavioral sciences poses little or no risk to the subject.

Federal regulations also stipulate that potential risks must be minimized to the extent possible, consistent with sound research design.

4.4: Minimizing and Managing Risk

4.4.1: When the Primary Source of Risk is the Data

When a possible disclosure of subjects' responses is the primary source of potential harm, safeguarding the data from unauthorized access can be accomplished in various ways including:

1. Collect data without identifiers.
2. Remove all direct identifiers as soon as possible.
3. Substitute codes for identifiers.
4. Maintain code lists and data files in separate secure locations.
5. Use accepted methods to protect against indirect identification, such as aggregate reporting or misleading identifiers.
6. Use and protect computer passwords.
7. Access and store data on computers without Internet connections.

4.4.2: Certificates of Confidentiality.

[Certificates of Confidentiality](#) are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. Certificates of

Confidentiality may be secured for any research, regardless of funding. The research does not have to be funded by NIH.

Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

A Certificate of Confidentiality will allow the investigator, and others who have access to research records, to be protected from disclosing identifying information on research participants in

- Civil.

- Criminal.

- Administrative.

- Legislative, or other proceeding, whether at the federal, state, or local level.

The kinds of information that can be protected include:

- Substance abuse or other illegal behaviors.

- Sexual attitudes, preferences, or practices.

- Genetic information.

- Psychological well-being.

Certificates of Confidentiality do not override the requirement to report the suspicion of child abuse or neglect, or any other state mandated reporting requirements, such as elder abuse.

4.4.3: Managing Other Risks

Subjects may be placed at risk simply by being involved in a study on a stigmatizing or illegal activity. One way to diminish their risk of exposure is to consider applying for a waiver of documentation of consent, if the consent form is the only document that links them to the study.

It may be necessary to find ways to guard against a subjects being observed participating in a study. For example, if an investigator is conducting a case study of a gang member, it may be necessary to find places to meet where other members of the gang could not observe the interaction.

Subjects may also be placed at risk by the nature of the inquiry. Studies on strategies for recovery from post-traumatic stress disorder, for example, may involve a complete assessment of the nature and impact of the trauma. In research that has the potential to be distressing to the subjects, investigators need to plan appropriate resources such as supportive counseling, referral, or access to research staff.

4.5: Consent Issues

Potential research subjects need to be given sufficient information to make a decision about whether they are willing to accept potential risks.

If questions will be of sensitive nature, subjects need to be forewarned.

Subjects also need to know what steps will be taken to protect confidential information, including disposition of recorded material.

Any limits to the extent to which a researcher can protect identifiable personal information should be clearly explained. State and local laws may limit confidentiality, such as reporting requirements for child and elder abuse. Confidentiality cannot be guaranteed for information shared in a focus group.

Summary

Focusing on the research methodology and/or topic alone in assessing risk is insufficient since it neglects to take into account another source of risk – that associated with findings or impact of the research results on subjects themselves or specific groups or communities. Common social and behavioral science methodologies such as surveys, questionnaires, and interviews are considered (sometimes erroneously) low risk since they do not involve physically invasive procedures with associated risk of physical harm. However, it is not the procedures *per se* that engender potential harm, but the interaction of different elements, including the research topic and the population being studied.

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Chapter 5: Informed Consent

Introduction

There is general consensus on the importance of informed consent. Most people have the reasonable expectation that they be treated with respect as autonomous individuals. They also expect that they have a right to make decisions about what will and will not be done to their persons and about what information they will share with others. As a reflection of this general consensus, substantial portions of the federal regulations are devoted to the consent process.

However, researchers are keenly aware that there are circumstances in which obtaining and documenting consent may be a complex, and often challenging, process. For instance, potential subjects may be illiterate. Or researchers may not be able to achieve scientifically valid results if they have to disclose the purpose of a study. Or asking subjects to sign consent forms linking them to a study about illegal activities could put them at risk of harm

The federal regulations provide sufficient flexibility to address some of these concerns, particularly for research with no more than minimal risk, including waivers and alterations of the consent and documentation processes.

5.1: Overview of Informed Consent

The regulations require that legally effective informed consent be obtained from the subject or the subject's legally authorized representative. They also make an important distinction between the process itself and the documentation of the process.

5.1.1: The Process

Informed consent is a process that begins with recruitment and screening of subjects and continues throughout the subject's involvement in the research. It includes:

- Providing specific information about the study to subjects in a manner comprehensible to them.

- Answering questions to better ensure subjects understand the research and their role in it.

- Giving subjects adequate time to consider their decisions.

Obtaining the voluntary agreement of subjects to participate in the study. The agreement is only to enter the study, as subjects may withdraw at any time, or decline to answer specific questions or complete specific tasks.

5.1.2: Documentation

Documentation of consent, quite simply, provides a record that the initial process took place, including the format and content of the consent process.

Documentation of consent generally consists of a consent form signed by the subject or the subject's legal representative, but may also be recorded by other means (for example, audio or videotape), as approved by an Institutional Review Board (IRB).

5.2: Information that Must Be Provided to Subjects

5.2.1: Essential Elements

1. Information that the study involves research.
 1. An explanation of the purposes of the research and expected duration of the subject's participation
 2. A description of the procedures to be followed.
 3. Identification of any procedures that are experimental.
2. A description of any foreseeable risks or discomforts to the subject.
3. A description of the benefits to the subject or to others.
 1. Note: *Research often has no direct benefit to the subjects. If there are no benefits, the investigator may tell subjects what he or she hopes to learn, how that knowledge will contribute to the field of study, or may perhaps benefit others, if indeed such cases can be made.*
4. A disclosure of any alternative procedures or treatments that may be advantageous to the subject.
 1. Note: *This requirement is primarily relevant for biomedical research; however, it might be applicable to social and behavioral sciences if behavioral interventions are proposed.*
5. A description explaining how the institution/investigator will maintain confidentiality of records.
 1. Note: *The description must include a full disclosure of any state mandated reporting requirements, such as suspicion of child abuse and/or neglect or harm to others, when warranted by the topic under investigation. State requirements vary, so IRBs need to be aware of state-specific information. See chapter 6, Privacy and Confidentiality, for a more in-depth discussion.*
6. For research involving more than minimal risk, a description of compensation provided and an explanation regarding whether medical treatment is available.
 1. Note: *This element applies primarily to biomedical research; however, if it is anticipated that subjects may experience emotional*

stress, for example, in a study about post traumatic stress disorder, a discussion about options for support and referral might be required by an IRB.

7. Contact information for individuals the subject may contact for further information about the research study and about the rights of research subjects. If research-related injury is possible, subjects must be told whom to contact should injury occur.
 1. Note: *In field research or in research in developing countries, there may not be any way for subjects to call or e-mail anyone. Alternatives must be developed, such as a local contact on the research team.*
8. A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits, and that the subject may discontinue at any time.
 1. Note: *The use of the word “penalty” is not necessary. Most researchers are not in a position to impose penalties. Furthermore, to say “there will be no penalty if you choose not to be in this study” would be inappropriate, and perhaps disturbing, when approaching community members for interviews about their perceptions of evolving race relations. On the other hand, if there is a power differential between investigators and subjects, such as teachers and students, or between subject groups, such as employers and employees, an explicit statement must be included in the consent form indicating that there will be no negative consequences. For example, “Your employer will not know whether you chose to participate in the study.”*

All consent forms must state explicitly that subjects may withdraw at any time and may choose not to answer questions or complete specific tasks. In keeping with this requirement, web-based surveys must be designed so that subjects are not forced to respond to a question before moving to the next one.

5.2.2: Additional Elements

Depending upon the nature of the research and the risks involved, IRBs may invoke additional regulatory requirements, such as:

1. A description of costs a subject might incur.
For example, transportation to support group or childcare costs.
2. A statement that any significant new findings that might relate to a subject’s willingness to participate will be provided to the subject.
For example, the effectiveness of an intervention.
3. Consequences of a subject’s decision to withdraw from a study, including how compensation will be affected.
Subjects need to know, for example, how their compensation will be affected if they choose not to complete an interview. If an institution uses a subject pool of students, the subjects will need to know how many credits

they will receive for their participation and under what circumstances they will receive partial payment.

4. A statement that there may be unforeseeable risks.
Primarily for biomedical research involving medical treatments and procedures.

5.2.3: Recruitment

Recruitment is part of the consent process, since it begins the disclosure process. Thus all recruitment strategies—such as fliers, e-mail messages, newspaper ads, phone calls, and so on—must be reviewed by an IRB before they are implemented.

5.2.4: Exculpatory Language

Subjects may not be asked to waive or even appear to waive any of their legal rights. They may not be asked to release an investigator, sponsor, or institution from liability for negligence. However, institutions may provide information about how liabilities are covered.

5.3: Waivers of the Elements of Consent

Federal regulations allow for a waiver or alteration of any or all of the elements of consent provided if, and only if, four criteria are met. These waivers allow researchers to modify the consent process by omitting one or more elements of information or to provide no information at all. Obviously a waiver of the entire process can not approved without significant consideration, but it is allowed under the regulations.

5.3.1: Criteria for Waiver

The four criteria for a waiver of any of the required elements of informed consent are:

1. **The research involves no more than minimal risk to the subjects.**
 1. “Minimal risk” means that “the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests.”
2. **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**
 1. Subjects do have certain legal rights. For example, parents have legal rights with regard to research with their school-aged children. In the absence of legal rights, this criterion is often difficult to apply because “rights and welfare” are not defined in the regulations.

2. Parties involved in the research process—researchers, IRBs, and the community of subjects—may not always agree on how to define subjects' rights and welfare.
3. **The research could not practicably be carried out without the waiver or alteration.**
 1. Impracticable does not mean time consuming, expensive, or inconvenient. Researchers will have to provide acceptable evidence to his or her IRB that securing consent is not feasible, regardless of cost and time.
4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation. This process is often referred to as “debriefing.”**
 1. The debriefing process is an opportunity to provide subjects will information not disclosed during the initial consent process, for example, in research that involves incomplete disclosure of the purpose of the research.

5.3.2: Common Uses of Waivers in Social and Behavioral Sciences

Waivers are often needed when research involves incomplete disclosure, deception, or covert observation.

Incomplete Disclosure: In social and behavioral sciences research, the requirement to describe the purpose of the research may be waived in order to counter the “demand effect.” If subjects know what a researcher is looking for, they may be inclined to provide it. (Alternatively, they may be less inclined to provide it.)

Deception : Outright deception can sometimes be justified as essential for investigating a particular phenomenon. For example, subjects may be told that a study is about perception of visual phenomenon, when in fact it is about susceptibility to pressure from the researcher’s confederates.

Observation: If people know their behavior is being observed, they may alter their behavior in such a way that obtaining meaningful results is not possible. Covert observation requires a waiver of all of the elements of consent.

5.3.3: Case Study: Applying the Waivers of Elements of Consent

A researcher is studying the effects of priming on performance on cognitive tasks. The first activity in the study will consist of a game in which subjects are asked to find words imbedded in a matrix. Two sets of words will be used: one designed to prime subjects positively, and one negatively. Subjects cannot be told the purpose of the activity, and the activity must be introduced in a way that deflects attention from its purpose. Thus, disclosure will be incomplete and the researcher intends to employ deception. The subjects are students.

In accordance with the regulations, as described above, IRBs must ask four questions:

1. Does the research involve no more than minimal risk to the subjects?
The priming game and the cognitive tasks pose no more than minimal risk.
2. Will the waiver or alteration adversely affect the rights and welfare of the subjects?
The subjects' welfare will not be adversely affected by the research activities as they are of no more than minimal risk. The subjects' right to participate in a fully informed consent process has been compromised, but is not likely that the subjects would experience the deception as a violation.
3. Could the research practicably be carried out without the waiver or alteration?
No. Disclosure of the purpose of the priming task would invalidate the research.
4. Would it be appropriate to provide subjects with additional, pertinent information after the research is complete?
Debriefing is appropriate and could provide a learning experience for the students about both the research process and (if they are given research results) factors affecting performance.

5.4: Ensuring Comprehension of Consent Information

Researchers are required to provide information to subjects in a manner comprehensible to the subjects. Some considerations regarding comprehension are discussed below.

5.4.1: Reading Level

Consider the following phrases that were included in actual consent forms:

“We are interested in the negotiation and articulation of gender roles within your community.”

“We are studying the efficacy of dyadic modalities in problem solving exercises.”

“Goals are postulated to exist within hierarchies.”

Although experts may understand these statements, most readers would be baffled. Even terms such as “focus group” and “intervention” are specialized terms. Consent forms should avoid jargon and be written at an appropriate reading level. It is estimated that the average reading level of Americans is the

eighth grade; however, many read at a much lower level. It is important to keep in mind that the consent form is an educational document, not a legal document.

When a study is complex and/or the reading or educational level of the prospective study population is low, the role of dialog becomes an even more crucial part of the consent process. Investigators should ensure comprehension to the best of his or her ability. Techniques for gauging comprehension include both eliciting questions from subjects and asking questions, for example, “Could you describe in your own words what the study is about and what you will be asked to do?”

5.4.2: Language Issues

The consent process should be conducted in the subject population’s primary language and the consent forms should be translated into that language. An IRB may require independent confirmation of the accuracy of the translation.

5.4.3: Cultural Issues

Comprehension may be affected by cultural differences other than language, such as comfort in asking questions of the researcher. For example, a doctoral student who had lived in Haiti for years prior to becoming a researcher, enlisted a community member to assist in the consent process. He knew that his potential subjects would be more comfortable asking questions of a compatriot than of him, even though he was fluent in Creole. (After the initial consent process, he left the premises for a sufficient period of time to allow questions to be asked.)

5.4.4: Layered Consent

Sometimes subjects may need to choose among several options. For example, they may agree to be interviewed but not agree to be videotaped. In the same study they may need to decide whether they wish their real names to be used. These options must be easy to select when the subject is signing the form. Separate signature lines for each option often are used, as are boxes to check and initial.

5.4.5: Use of Second Person

Consent forms should be written in the second person, as if the researcher were conversing with the potential subjects. For example, “If you agree to be in the research, you will be asked to complete four surveys that are designed to...” The use of the first person (for example “I understand ...”) is not recommended because it can suggest that the discussion is over and may discourage, rather than encourage, dialogue with the investigator.

The use of pronouns should be consistent throughout the information portion of the form, and not shift from “you” to “I” to “one” to refer to the subject. However, it

is typical to use “I” to refer to the subject in the acceptance/signature portion of the form. For example, “I have read the description of the research, and I have been given the opportunity to ask questions...” A line or space should separate the information portion of the form from the acceptance/signature portion.

5.4.6: Format

If the material is complex and/or the IRB anticipates that subjects may have difficulty understanding the material, the IRB may suggest that researchers format their consent forms so they are easier to read and understand.

Techniques such as the following can help to achieve that goal:

- Bold-faced titles within the document.
- Headings that describe the basic structure of the study, for example, “You will be asked to complete three questionnaires” as a heading followed by more information about when, where, and how long.
- Liberal use of white space.
- Legible font size.
- Bulleted lists.

5.5: Ensuring Free Choice

The principle of respect for persons requires that participation in research be truly voluntary, and free from coercion or undue influence. Even when a study is innocuous, subjects must be informed that they do not have to participate, they may choose not to answer particular questions or complete specific tasks, and they may choose to stop participating at any time.

5.5.1: Setting and Time

Investigators should consider ways in which the setting of the consent process might include elements of coercion. Potential subjects in the following situations might not feel entirely free to choose:

Adolescents whose parents are in the room.

Adolescents in a group of other adolescents being recruited for the same study.

Parents who receive a letter from the principal asking them for permission to enroll their children in a study.

Athletes recruited under the watchful eye of their coach.

Undocumented immigrants facing an official-looking person at their door.
Employees asked to participate by their employer.

Subjects must be given adequate time to consider whether or not they wish to participate in a study. This is particularly true if a study has more than minimal risk or will require subjects to disclose sensitive information.

5.5.2: Compensation

Compensation refers to payments or gifts offered to subject as reimbursement for their participation. Compensation may become coercive if it is so high as to override other considerations for potential subjects. Determining whether compensation is coercive depends on the research context and the financial and emotional resources of the subjects. A potential problem is that if compensation is too attractive, subjects might misrepresent themselves in order to participate in a study.

5.6: Informed Consent in Exempt Research

If an institution determines that a study meets the criteria for exempt research, the regulatory requirements for informed consent do not apply. However, research that is exempt from federal regulations is not exempt from ethical standards as outlined in the Belmont Report. Potential subjects in exempt research must be fully informed and free to choose whether to participate.

5.7: Documentation of Informed Consent

When documentation is required, there are two methods available:

1. The subject or the subject's legal representative signs a form containing all the required elements of consent and any other elements necessary to provide complete disclosure. The person who signed the consent form is given a copy as a reference and a reminder of the information conveyed.
2. The consent is done orally and is documented by an impartial witness. The witness must document 1) that the process occurred, and 2) the content of the process. This process is called the "short form written consent process" described in detail in the regulations. The "short form" refers to a summary of the consent information given to the subjects. Although they may not be able to read, they may have a family member or friend who may be able to do so. (This problem becomes moot if the subject population has no written language.) Consult your IRB if you are considering an oral consent process.

Note: Illiterate English-speaking subjects can "make their mark" on the informed consent document, as long as it is consistent with applicable state laws.

5.8: Waivers of Documentation

Documentation of the consent process is not always required. Note that waivers of documentation are **not** waivers of the consent process itself.

Documentation may be waived under two circumstances:

1. The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research, and the consent document is the only record linking the subject with the research. For example:

- Research about women who have left abusive partners, which assesses factors that affected their ability to leave.
- Research on the black market capitalist economy in Cuba in which illicit vendors will be interviewed in a safe space.

(Note that subjects must be given the option of receiving a document describing the research and the subjects' wishes prevail.)

2. Study participation presents minimal risk of harm to the subject and the research involves no procedures requiring consent outside the context of participation in a research study, for example:
 - A telephone survey by environmental educators hypothesizing that knowledge about the exploration of oil reserves in Utah's Red Rock National Park is positively related to proximity to the site and income level.

When the requirement for documentation is waived, the IRB may require the investigator to offer subjects information about the study in writing.

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Chapter 6: Privacy and Confidentiality

Introduction

The importance of protecting the privacy of research subjects and ensuring confidentiality of research data is widely acknowledged. The right to privacy is highly valued in the United States and secured by laws *other* than those for protecting research subjects. For example, The Family Educational Rights and Privacy Act (FERPA) are designed to protect the privacy of students' educational records. And the Privacy Rules of the Health Insurance Portability and Accountability Act (HIPAA) describes conditions under which researchers can access and use private health information.

Professional associations of social and behavioral sciences have adopted guidelines that include the need to respect the privacy of subjects. For example:

“Anthropological researchers must do everything in their power to ensure that their research does not harm the safety, dignity or privacy of the people with whom they work, conduct research or perform other professional activities.” ([Code of Ethics of the American Anthropological Association](#)) (Links will open new windows in your browser. To return to the module, close the new windows.)

“Psychologists respect the dignity and worth of all people, and the rights of individuals to privacy, confidentiality, and self-determination.” ([Ethical Principles of Psychologists and Code of Conduct, 2002](#))

See also, the [Oral History Association](#) and the [American Sociological Association](#).

It is important that researchers become adept at safeguarding the privacy and confidentiality of their subjects.

6.1: Definitions

“Privacy” refers to our right to control access to ourselves and to our personal information. It means that we have the right to control the degree, the timing, and the conditions for sharing our bodies, thoughts, and experiences with others.

“Confidentiality” refers to agreements made with subjects, through the consent process, about if and how information provided by the subjects will be protected. These agreements may include descriptions about whether identifiers will be retained, who will have access to identifiable data, and what methods will be used to safeguard data, such as encrypted storage or locked files.

Privacy is about individual rights; confidentiality is about information.

6.2: Private vs. Public Behavior

The federal regulations define “private information” to mean “information about behavior that occurs in a context in which an individual can reasonably assume that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).”

This definition offers a yardstick for differentiating between public and private behavior, and whether it is reasonable for subjects to expect privacy in a particular context.

It would be unreasonable to expect that behavior on a street corner is not public, but reasonable to assume that behavior in our homes is private. However, individuals may identify private spaces in the midst of very public ones. Consider the following two situations:

Parents taking their children to a city park might consider it a violation of privacy if the interactions of their children were filmed and used for research purposes. (They might be less likely to consider it such if their children’s behaviors were simply coded by observers.)

Members of an on-line support group might express dismay at being observed by researchers, even though the communications among group members could technically be accessed by hundreds of thousands of people. (This problem has actually occurred.)

There is a conundrum here for investigators and IRBs. Subjects’ expectations form the basis for making distinctions between public and private behavior — in other words, privacy is in the eye of the subjects. Yet the reasonableness of their expectations must be assessed in some way. Investigators and members of Institutional Review Boards (IRBs) members will have to make the judgment about what is private information based upon their knowledge of the population and the circumstances in which research will take place.

6.3: Controlling Access to Private Information.

Individuals’ ability to control access to their personal information and to their persons is determined by a variety of factors, including socioeconomic status, age, and circumstance. For example, information about welfare rolls is public information; information about personal stock portfolios is not (unless you are a government official). Minors have fewer rights to privacy than adults. Institutionalized persons may have significant limitations on their ability to control personal information.

6.6.4: Privacy and Research Methods

Concerns about privacy in the research context occur in several areas:

1. Methods used to identify and recruit subjects.
2. Obtaining information through covert observation.
3. Privacy of third parties in research.
4. Privacy and study questions.

These topics are discussed in detail below.

6.4.1: Identifying and Recruiting Subjects

Methods used to identify subjects can constitute violations of privacy. For example, a recruitment technique referred to as “snowball sampling” involves asking an identified subject to provide the researcher with names of other individuals who have characteristics or experiences of interest to the researcher. The researcher then contacts those individuals.

Some people might find it a violation of privacy to be contacted by a researcher who knows something about them that they regard as personal and perhaps even sensitive (for example, adoptees). However, if the research topic is innocuous, the possibility of an invasion of privacy would be minimal. For instance, a researcher conducting an oral history project might recruit local retirees from a particular company for an oral history project.

There are circumstances in which being approached by a researcher in a public setting could violate potential subjects’ privacy, and perhaps even jeopardize their safety. For example, a researcher conducting a case study of a gang member could endanger her subject if she approached him in the presence of other members of the gang. Subjects’ privacy could also be violated if they are approached via a “not thoroughly confidential” method, such as the use of company e-mail. If such a method were used to recruit subjects about, say, obesity and depression, subjects’ privacy could be jeopardized.

6.4.2: Obtaining Information through Covert Observation

Privacy issues arise in regard to information obtained for research purposes without the consent of subjects, such as through observational studies including the following methodologies:

1. Concealed devices used to record information for later analysis, for example, tape recording conversations or videotaping personal interactions.
2. Concealment of the researcher.
 1. Concealment of their person, for example, behind a one-way mirror, as the behavior of subjects is observed and recorded.

2. Concealment of their identity, for example, participant observation in which the researcher assumes a role in the setting or group being studied.

Observational studies raise serious ethical concerns when they access information that individuals might choose not to reveal, or take away individuals' rights to control information about them, regardless of how innocuous it may be. The following questions might be used to assess the ethical soundness of observational research:

1. Is private identifiable information being collected about subjects without their knowledge (for example, covert observation recorded on videotape) in a situation in which individuals could reasonably expect privacy? If it is, then the following questions would also arise:
 1. Would reasonable people be offended by such an intrusion?
 2. Can the research be redesigned to avoid the intrusion?
2. Would information gathered through covert observation place the subject at risk if disclosed?
3. Is any invasion of privacy justified by the benefits of the study? In other words, is the knowledge to be gained important enough to involve subjects without their consent?
4. What, if anything, will the subject be told later?

6.4.3: Privacy of Third Parties.

If a researcher plans to ask for private information about individuals other than the research subjects, he must determine if that practice would constitute an invasion of privacy. Consider the following situation:

A well-publicized study of twins asked young adult twins for information about their parents' mental health. One parent who opened a survey mailed to his child felt that his privacy had been violated and believed that his job security would be imperiled should there be a breach of confidentiality. Federal auditors agreed with his assessment. In this instance, the research could have been designed to avoid the intrusion, perhaps by questioning the parents directly.

Now consider a case where battered women are being interviewed. Such interviews might elicit a great deal of private information about the women's abusive partners. However, to require informed consent from the partners could place the women at great risk of harm. So a waiver of consent would be appropriate.

6.4.4: Privacy and Study Questions.

If a survey instrument contains questions that individuals might find to be invasive, they must be forewarned. Studies about sexual behavior, childhood

abuse, use of psychotropic medications, and other personal topics should include a disclosure in the consent form about the nature of the questions

6.5: Confidentiality

6.5.1: The Agreement

The ways in which data will be used and made available to others is part of the agreement researchers make with study participants. Confidentiality procedures and limits to confidentiality must be spelled out during the consent process and in the consent form. Researchers must then abide by the agreement.

6.5.2: Confidentiality Procedures.

Confidentiality procedures should be both necessary and sufficient. Some studies in the social and behavioral sciences are about innocuous topics, don't collect subjects' names, and result in data sets from which no one could extract any identifiers. Once these matters are explained to subjects and the data are collected, confidentiality can be assured without additional confidentiality procedures.

If data are individually identifiable, if the research topic is sensitive, if subjects will be taped, or if the researcher plans to use the data for purposes other than those of the original study, ensuring confidentiality may require more complex procedures.

The following questions may be used to guide the design of procedures to safeguard subjects and their data:

1. Who will have access to study data in the present **and** in the future?
2. Are identifiers really needed?
3. How will data be reported? In aggregate? Using pseudonyms? Using real names?

If audiotapes or videotapes are made, what will be done with them during and after the research? Will they be shown at scholarly conferences? Used to train graduate students? Archived? Will they be saved in case they have a research use as yet unknown?

4. How will the data be protected from inadvertent disclosure or unauthorized access?
5. Can identifiers be destroyed, thus anonymizing the data?
6. If participation in the study could put people at risk, for example, sex workers subject to police harassment, has the requirement for documentation of consent been waived?

7. Does sensitive data need to be protected from subpoena by third parties? Should a Certificate of Confidentiality be obtained?

6.5.3: Indirect Identifiers

It is often possible to identify subjects indirectly based on combinations of demographic data. For example, the number of Asian female varsity athletes at a particular university might be small. Or there may be only a few Caucasian managers over 40 who have been employed in the marketing department of a mid-sized company for five years.

Using individual-level data when reporting research results could violate subjects' expectations of privacy and agreements about confidentiality. Such an outcome could be damaging if the study were about sensitive topics such as the use of steroids or employee assessments of their managers.

6.5.4: Research Using Existing Data Sets

Existing data sets containing individual-level data are available from a number of public and private sources. In some cases, individuals could be identified indirectly due to the number of available data points. Some providers of data will require that researchers receive IRB approval for confidentiality procedures if the subjects could be identified and if the exposure could harm them in some manner, or violate the agreement made with subjects when the data were collected.

6.5.5: Limits to Confidentiality

There are often limits to the confidentiality investigators can offer subjects. These limits should be spelled out during the consent process.

6.6: State Laws

6.6.1: Child Abuse Reporting.

Most states require that investigators report the suspicion of child abuse and neglect. This requirement should be described when child abuse and neglect might be revealed in a study. Such studies could involve at-risk youth, school-based interventions, or parenting practices, among others.

On the other hand, there are many studies in which it is extremely unlikely that the topic would arise or that the researcher would be in a position to observe neglect or abuse. For example, a study of decision-making strategies using computer-based activities would not generate information about child abuse and there would be no need to discuss reporting requirements during the consent process.

6.6.2: Other State Reporting Laws.

State reporting laws may cover such matters as specific communicable diseases, the intent to harm oneself or others, and elder abuse. Consult with your IRB about the laws in your state.

6.7: Certificates of Confidentiality.

[Certificates of Confidentiality](#) are issued by the National Institutes of Health (NIH) and other institutions to protect identifiable research information from forced disclosure. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. A Certificate of Confidentiality will allow the investigator and others who have access to research records to refuse to disclose identifying information on individual research participants in civil, criminal, administrative, legislative, or other proceedings, whether at the federal, state, or local level.

6.7.1: Information that can be protected includes, but is not limited to:

- Substance abuse or other illegal behaviors.
- Sexual attitudes, preferences, or practices.
- Genetic information.
- Psychological well-being.

Certificates of confidentiality may be secured for any research, regardless of funding. The research does not have to be funded.

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