Ethical Protection of Research Participants

International Institute for Reproductive Loss
Priscilla K. Coleman, Ph.D.

Introduction

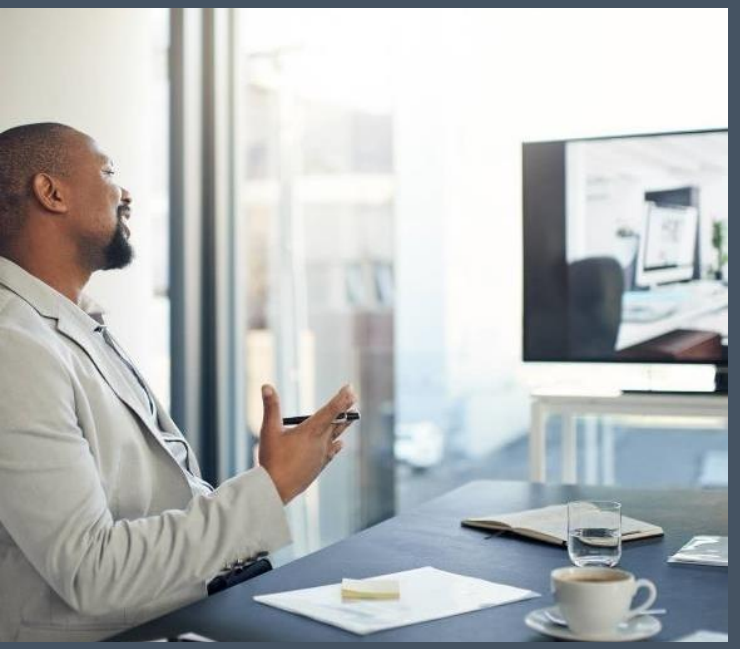
Human subjects research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge. Data collection and/or analysis with human subjects is technically considered “Research” by the U.S. Federal government if it is not anonymous and there is a plan to share the information publicly.

A systematic investigation is a project that involves a plan for studying a topic, exploring a research question, or developing a theory that may include (but is not limited to) collection of the following forms of quantitative or qualitative data:

- Surveys
- Testing procedures and results
- Evaluation procedures and results
- Interviews or focus groups
- Experimental designs including clinical trials
- Observation of individual or group behavior

Introduction

All research protocols should be scrutinized by an Institutional Review Board (IRB) prior to data collection/dissemination to ensure protection of participants' psychological and physical well-being and to maintain their privacy. The purpose of this presentation is to offer an overview of U.S. history of ethical protection of human research participants and to describe contemporary practice.



History of Ethical Conduct of Research with Human Subjects in the U.S.

U.S. regulations to protect people involved in research are the result of several 20th century examples of doctors and scientists abusing public trust and causing harm to many individuals.

- Beecher (1966), whose training was in medicine and research, published a widely cited *New England Journal of Medicine* article describing many examples of unethical treatment of human participants conducted at various U.S. institutions.
- Syphilis Study in Tuskegee, Alabama Public Exposé in 1972. For several decades beginning in the 1930s, U.S. government doctors studied the evolution of untreated syphilis in poor African American men. The diagnosis was not shared with the men and no treatment was offered before or after penicillin became available as a cure.

The Belmont Report

The Belmont Report

Public outcry related to research abuses resulted in the *Belmont Report* published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on April 18, 1979. This Commission was the result of the National Research Act of 1974, and those appointed were charged with identifying the basic ethical principles that should be employed as the basis for conducting biomedical and behavioral research with human participants. Guidelines were also developed to assure that research is conducted in accordance with the basic principles.

The Belmont Report

The Commission was specifically directed to consider: “(i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (iii) appropriate guidelines for the selection of human subjects for participation in such research and (iv) the nature and definition of informed consent in various research settings.”

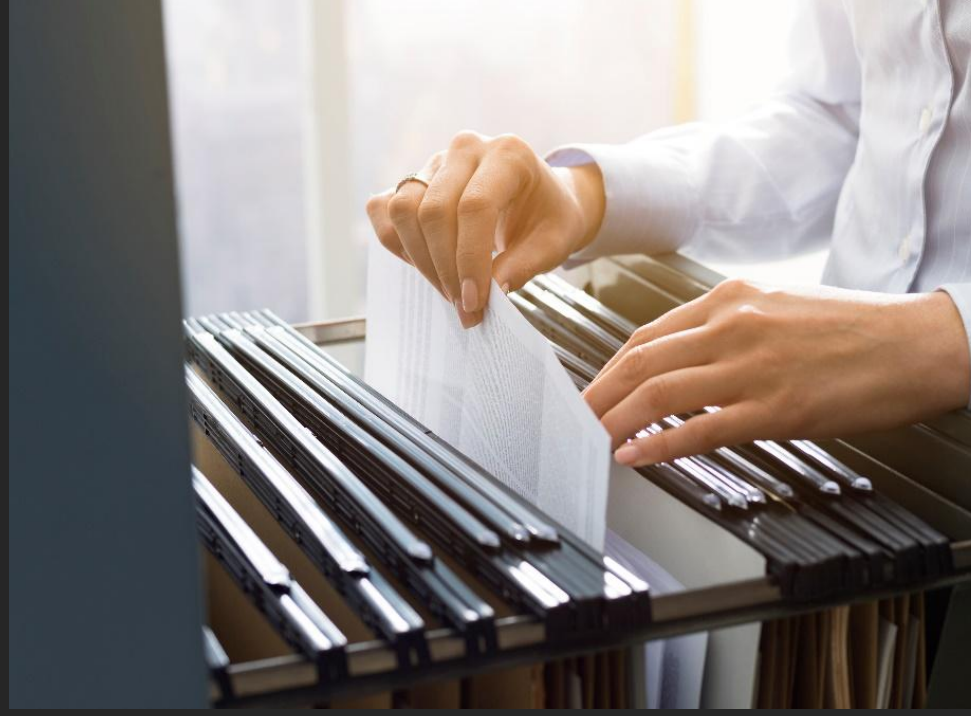
The Common Rule

U.S. Federal rules developed to protect participants in research were published by the Department of Health and Human Services (HHS) in 1991.

The first section is referred to as the “Common Rule” because it was simultaneously adopted by 15 Federal departments and agencies.

The Common Rule was subsequently revised in 2017 taking into consideration contemporary changes in the conduct of research.

One key protection in the “Common Rule” is the requirement for appropriate review and approval of research by Institutional Review Boards.



The Common Rule:
The Overall Goals of the Federal Policy

As noted by the U.S. Department of Health and Human Services, all organizations and institutions engaged in research should foster a culture of ethical research, which rests on three principles:

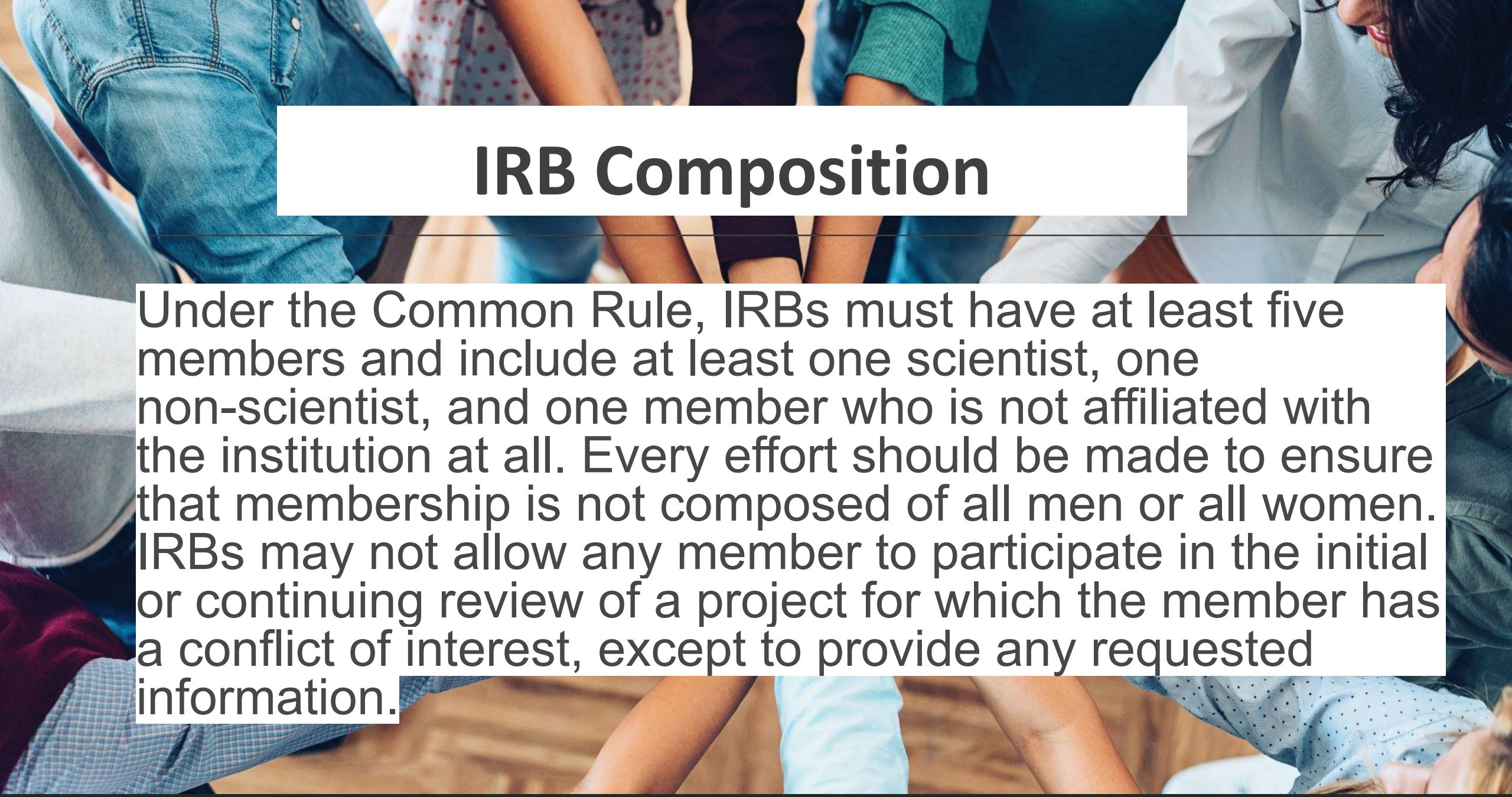
1. "RESPECT for persons' autonomy, meaning the researcher gives adequate and comprehensive information about the research and any risks likely to occur, understandable to the participant, and allows them to voluntarily decide whether to participate.
2. BENEFICENCE, meaning the research is designed to maximize benefits and minimize risks to subjects and society.
3. JUSTICE, meaning that the research is fair to individual subjects and does not exploit or ignore one group (e.g., the poor) to benefit another group (e.g., the wealthy)."

Research produces many societal benefits. Regulatory oversight through the establishment of Institutional Review Boards ensures that potential harm of the research is balanced by potential benefits.

What is an Institutional Review Board (IRB)?

Under federal regulations, an IRB is a committee that has been formally assigned to review and monitor research with human subjects. An IRB has the authority to approve, require modifications, or disapprove of research. IRBs play an essential role in the protection of the rights and welfare of individuals participating in research.

IRBs provide both advance approval for a study and periodic review to ensure the rights and welfare of humans participating as subjects in research are protected. Research protocols outlining the planned research and related materials including informed consent documents are submitted to the committee.



IRB Composition

Under the Common Rule, IRBs must have at least five members and include at least one scientist, one non-scientist, and one member who is not affiliated with the institution at all. Every effort should be made to ensure that membership is not composed of all men or all women. IRBs may not allow any member to participate in the initial or continuing review of a project for which the member has a conflict of interest, except to provide any requested information.

Traditional vs. Independent IRBs

Traditional: For decades, academic institutions, medical centers, and hospitals have maintained their own internal IRBs to review the research of affiliated investigators.

Independent: IRBs that have been developed to provide review services to investigators who are not affiliated with an institution that has its own IRB. These IRBs under the same federal and state regulatory requirements as the traditional IRBS.

IRB General Responsibilities

IRBs weigh many factors before approving proposals. Their main charge is to ensure the following:

- Risks to subjects are minimized and are reasonable in relation to expected benefits, if any, to subjects and the importance of the knowledge that is likely to result.
- Selection of participants is equitable.
- Informed consent will be sought from each prospective participant or the individual's legally authorized representative. Informed consent will be appropriately documented;
- When relevant, the research plan makes provision for monitoring the data collected to ensure the safety of subjects; and when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

IRBs and Assessment of Risk to Potential Research Participants

Projects are reviewed and monitored for the possibility of harm to subjects that is considered more than what is normally encountered in daily life. The Common Rule defines minimal risk as that involving both the probability and magnitude of physical or psychological discomfort/harm, not greater than what people experience as they go about their daily activities or during the conduct of routine physical or psychological assessments.

This might include disclosure of confidential information to individuals who could potentially use it to harm an individual. Researchers who gather confidential information are ethically bound to take all reasonable measures to provide a secure environment for the storage of data and to make sure it doesn't fall into the wrong hands. Confidentiality should be guaranteed unless the respondent explicitly agrees to disclosure. The release of any information that can be linked to an individual, potentially damaging or not, should be agreed upon.

“Delayed Harm”

The concept of "Delayed harm" relates to the possibility of experiencing a longer-term psychological reaction, such as anxiety or depression. Interview content may lead subjects to re-examine past experiences differently, to reevaluate themselves negatively, or seek additional information that may result in additional difficulties. Researchers might be asked to provide an IRB with an estimate of the probability of harm that is of this nature and offer a plan to prevent or reduce the impact. For example, a list of counseling agencies can be provided for women who agree to an interview regarding an abortion experience that occurred several years prior.

When must a researcher or individual engaged in data collection or analysis seek IRB approval?

1) When there is a plan to share the data or analysis publicly. Public dissemination/presentation could be in the form of a journal article, a conference presentation, an organizational website, or in an educational seminar or intervention. IRB approval is needed even if the analysis will not contain any identifiable information about participants in the study.
2) Data collection or analysis is not completely anonymous. This includes any interaction or intervention with human beings or investigative efforts involving access to identifiable private information.

What are some examples of non-research involving human beings?

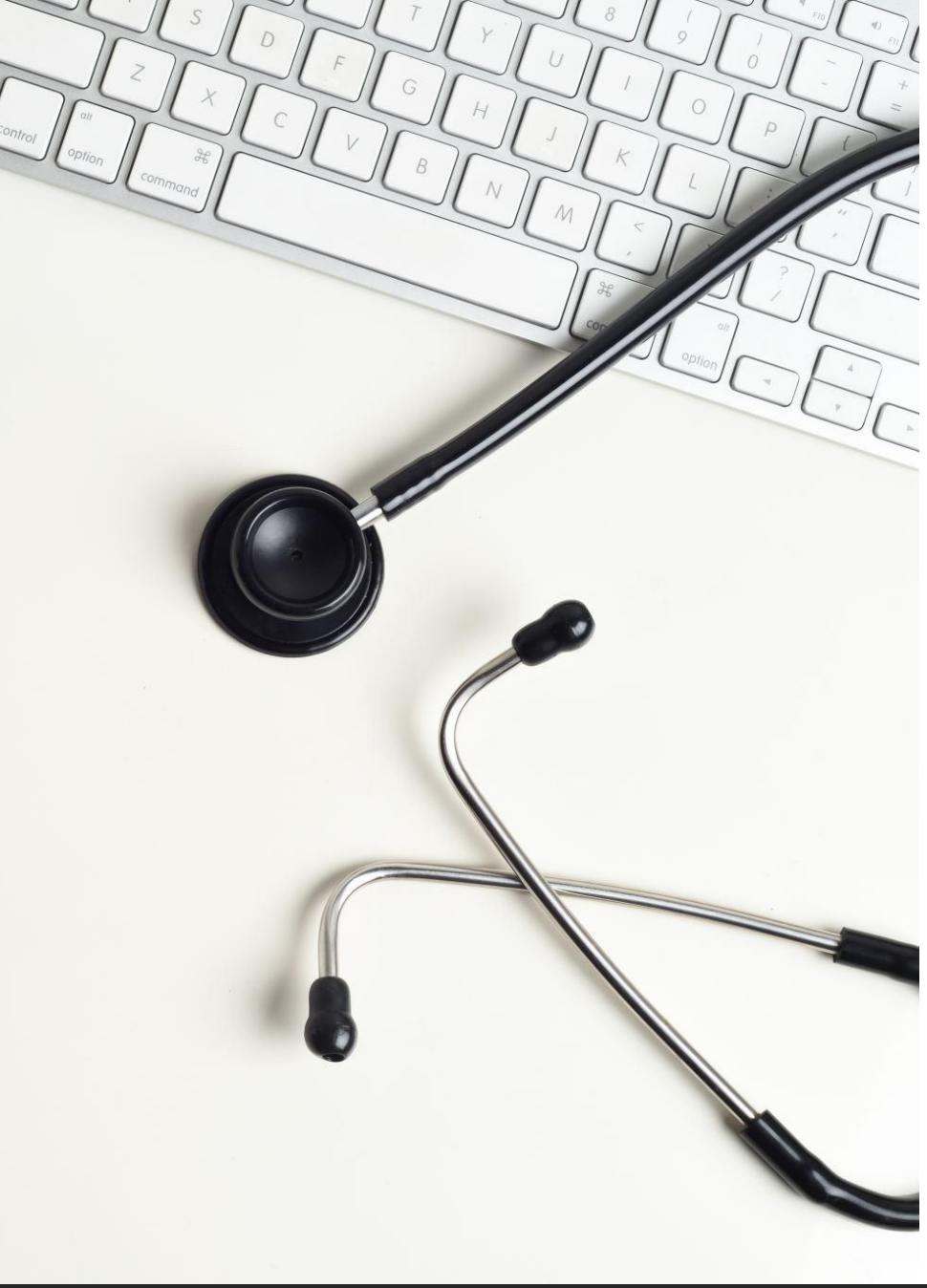
- **Public health or clinical intervention for which there is no public sharing of data.**

- **Data gathered about an employee for promotion purposes.**

- **An individual's choice to share information about herself or himself in a public forum.**

"Safety isn't expensive, it's priceless." – Author unknown.

"It takes leadership to improve safety." – Jackie Stewart.



Information Sources

The development of this PowerPoint presentation was primarily based on online content provided by the U.S. Department of Health and Human Services and the author's many years of experience conducting research and teaching research methods.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

https://www.hhs.gov/ohrp/index.html