

Workers as Research Subjects: A Vulnerable Population

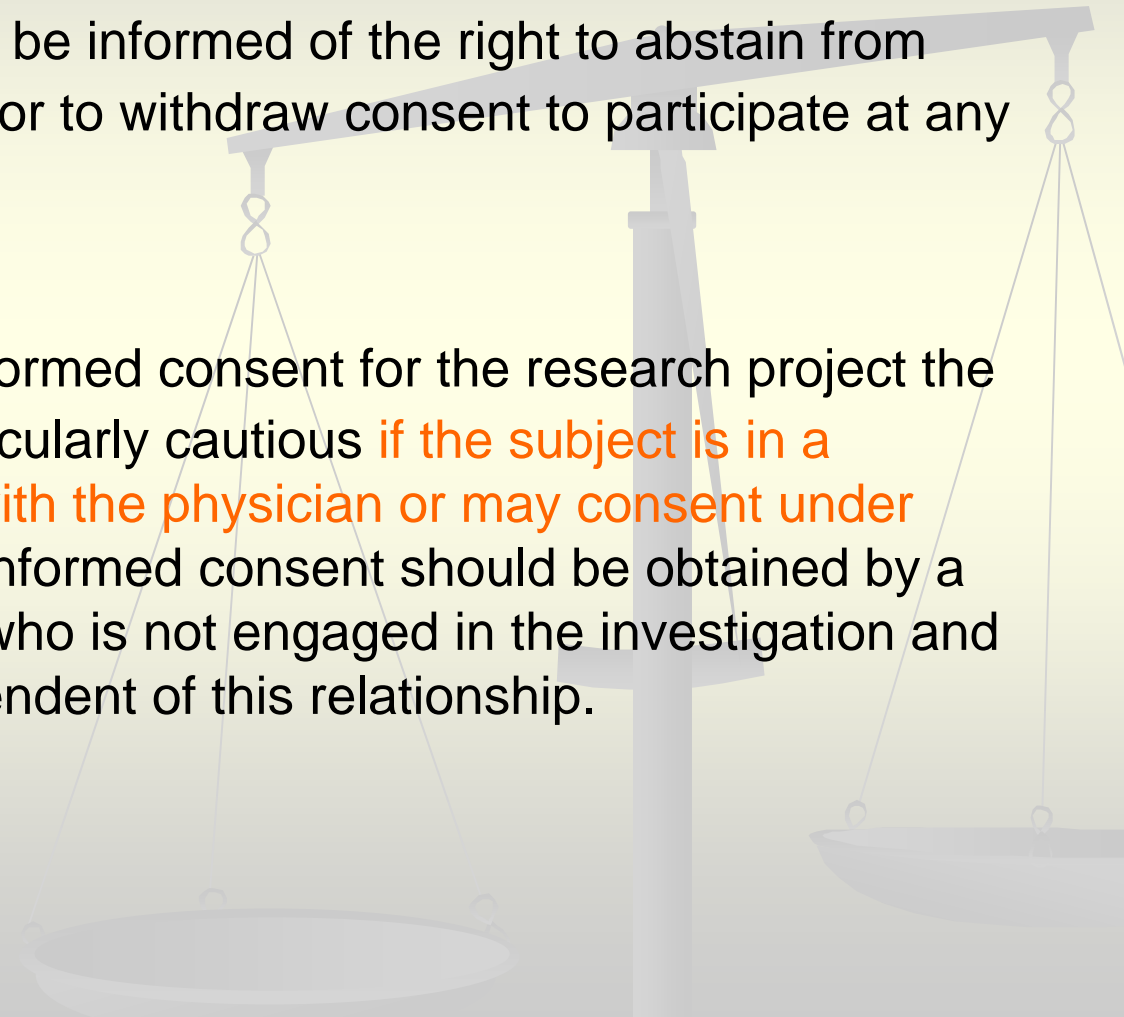
PAYCHECK VULNERABILITY

陳 明 醫師
彰化基督教醫院
遺傳諮詢中心


Declaration of Helsinki 2000

- 5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
- 8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.

Declaration of Helsinki 2000

- 
- **22.** The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time **without reprisal**.
 - **23.** When obtaining informed consent for the research project the physician should be particularly cautious **if the subject is in a dependent relationship with the physician or may consent under duress**. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

Belmont Report 1976

- By **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**
 - **Three Basic Ethical Principles:** respect for persons, beneficence, justice
 - **Three Requirements for Applications:** informed consent, risk-benefit assessment, selection of subjects of research
- 

FAST TRACK ARTICLE

Workers as Research Subjects: A Vulnerable Population

Susan L. Rose, PhD
Charles E. Pietri, BA

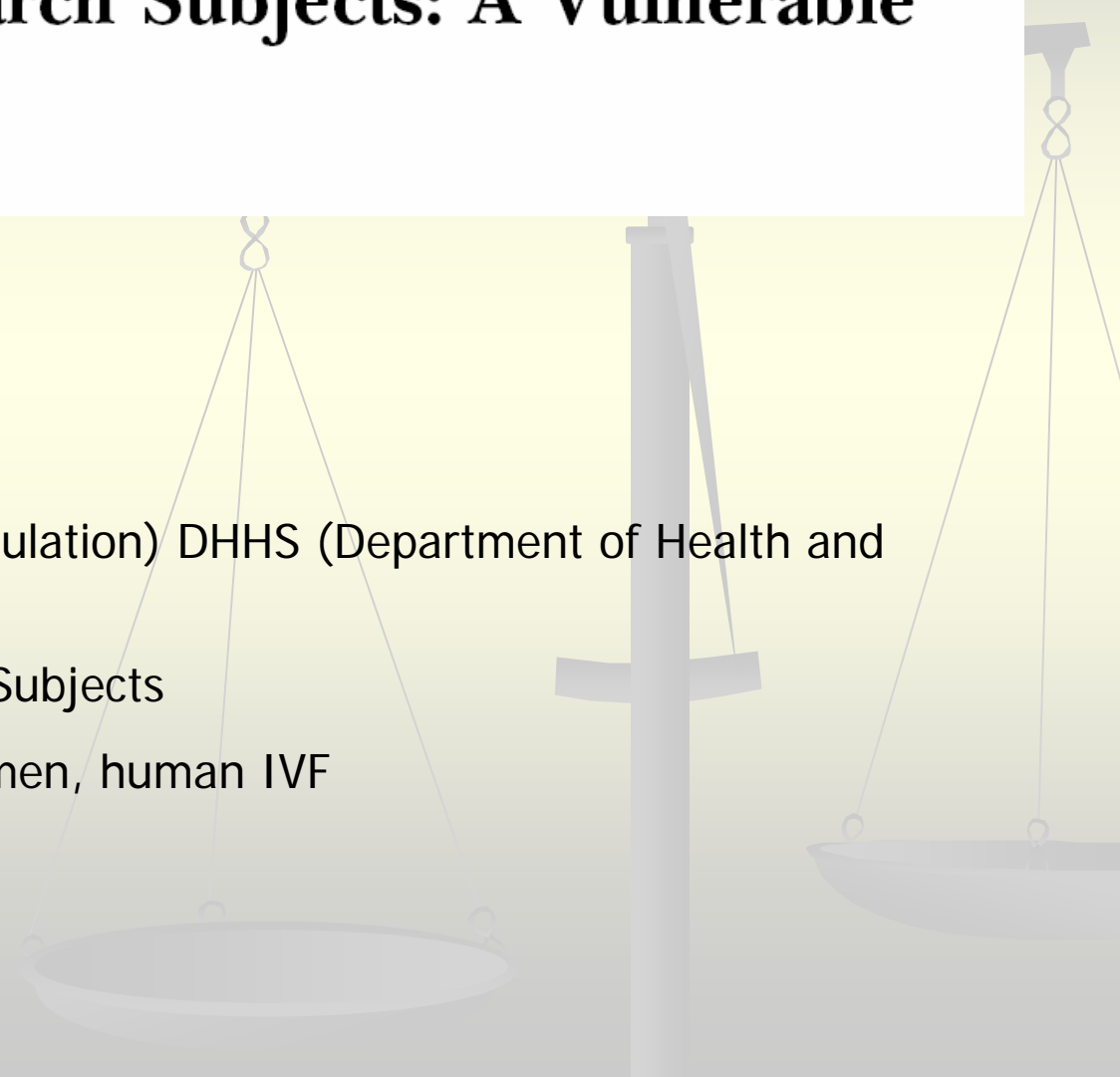
45 CFR (Code for Federal Regulation) DHHS (Department of Health and Human Services)

Part 46 Protection of Human Subjects

46.205 fetuses, pregnant women, human IVF

46.305 prisoners

46.407 children



Introduction

- 美國聯邦法規『研究受試者人權保護通則』規範了所有的研究者和研究單位都需要遵行的保護受試者人權的準則。在這個通則裡，特別提到了『弱勢族群』的保護。
- 所謂的『弱勢族群』是指某些特殊情境下，比較不能保護自己的人。

教育目標

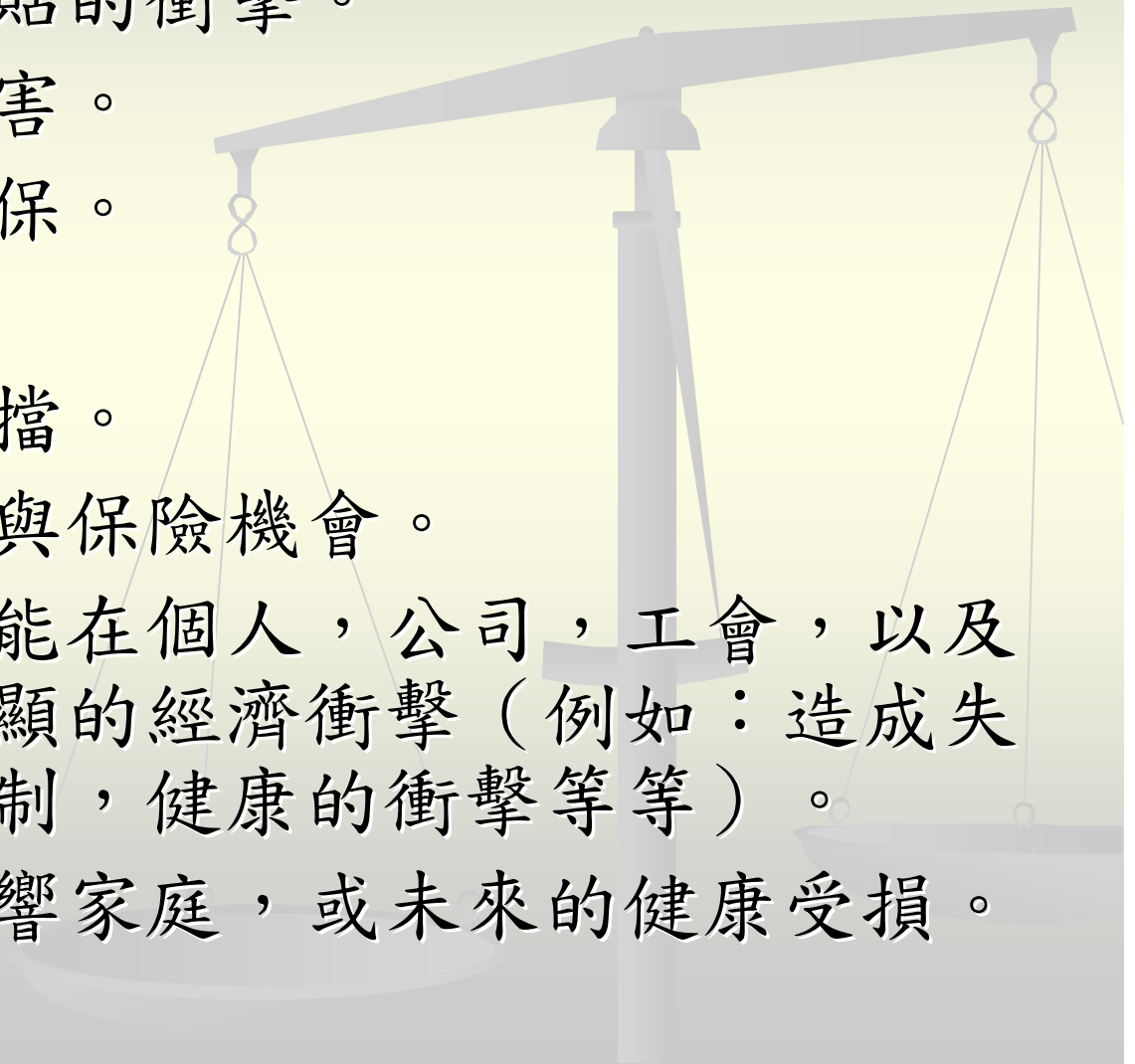
- 視員工受試者為弱勢族群。
- 提供員工受試者所需的特別的保護。
- 明白，『一般法則』不一定能夠針對員工做為受試者時給予適合的定義。
- 雖然員工可能因為政治或科學的理由成為受試者，我們仍然期待研究需要符合科學水準，也需要盡可能的符合一般法則的要求。



**Workers Are in Effect a
“Vulnerable” Population and
Subject to Employment
Related Risks.**

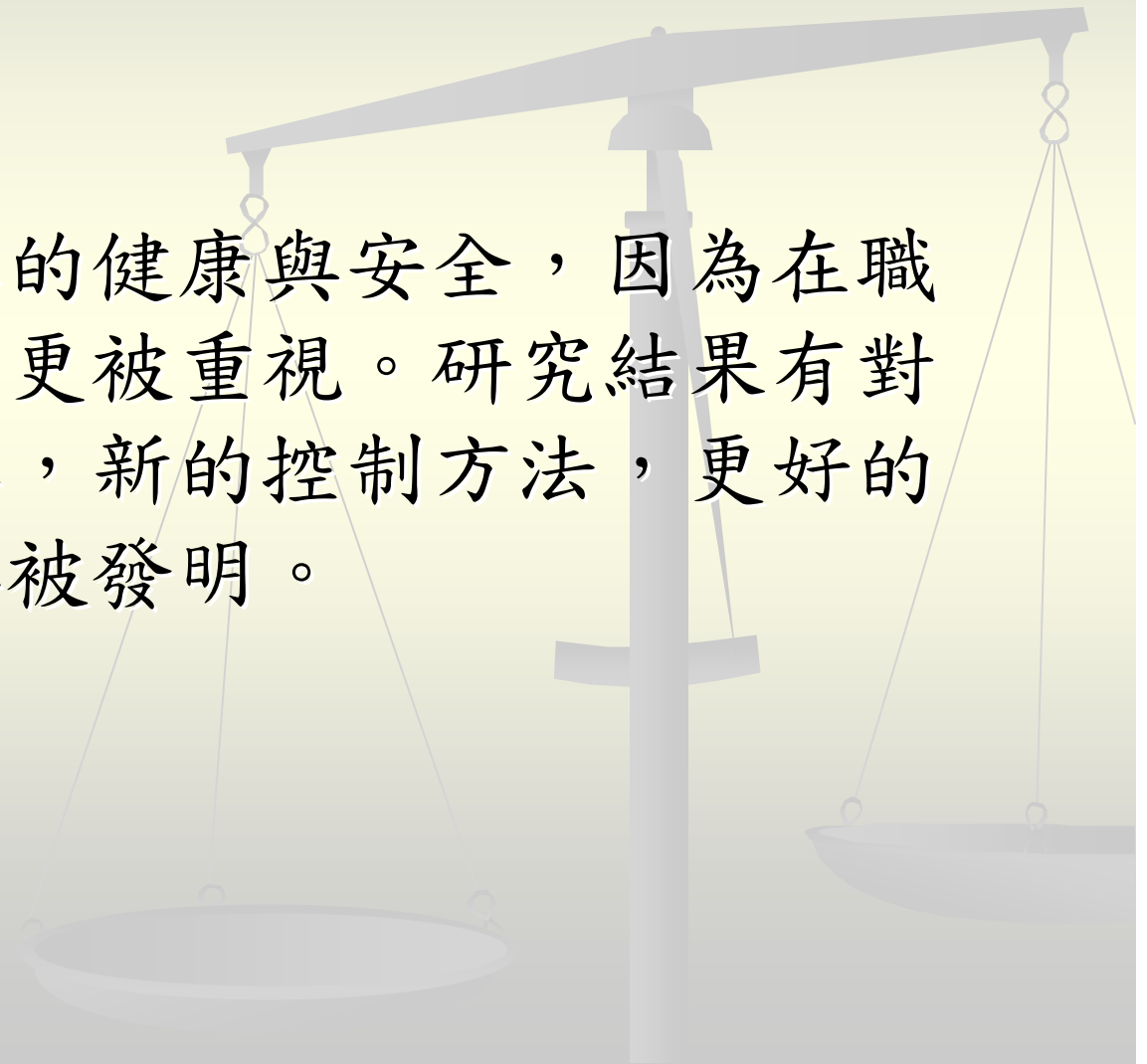
為什麼員工是『弱勢族群』？

- 對個人權利，津貼的衝擊。
- 家庭關係受到危害。
- 可能使得工作不保。
- 同儕壓力。
- 職位升遷受到阻擋。
- 取得或阻礙貸款與保險機會。
- 研究的結果，可能在個人，公司，工會，以及政府造成許多明顯的經濟衝擊（例如：造成失業，工作受到限制，健康的衝擊等等）。
- 基因研究可能影響家庭，或未來的健康受損。



我們為什麼需要這些研究？

- 幾十年來，員工的健康與安全，因為在職場的研究結果而更被重視。研究結果有對瞭解暴露的機轉，新的控制方法，更好的監控技術與器具被發明。



Worker Studies Require Review by the Institutional Review Board (IRB).

人體試驗委員會

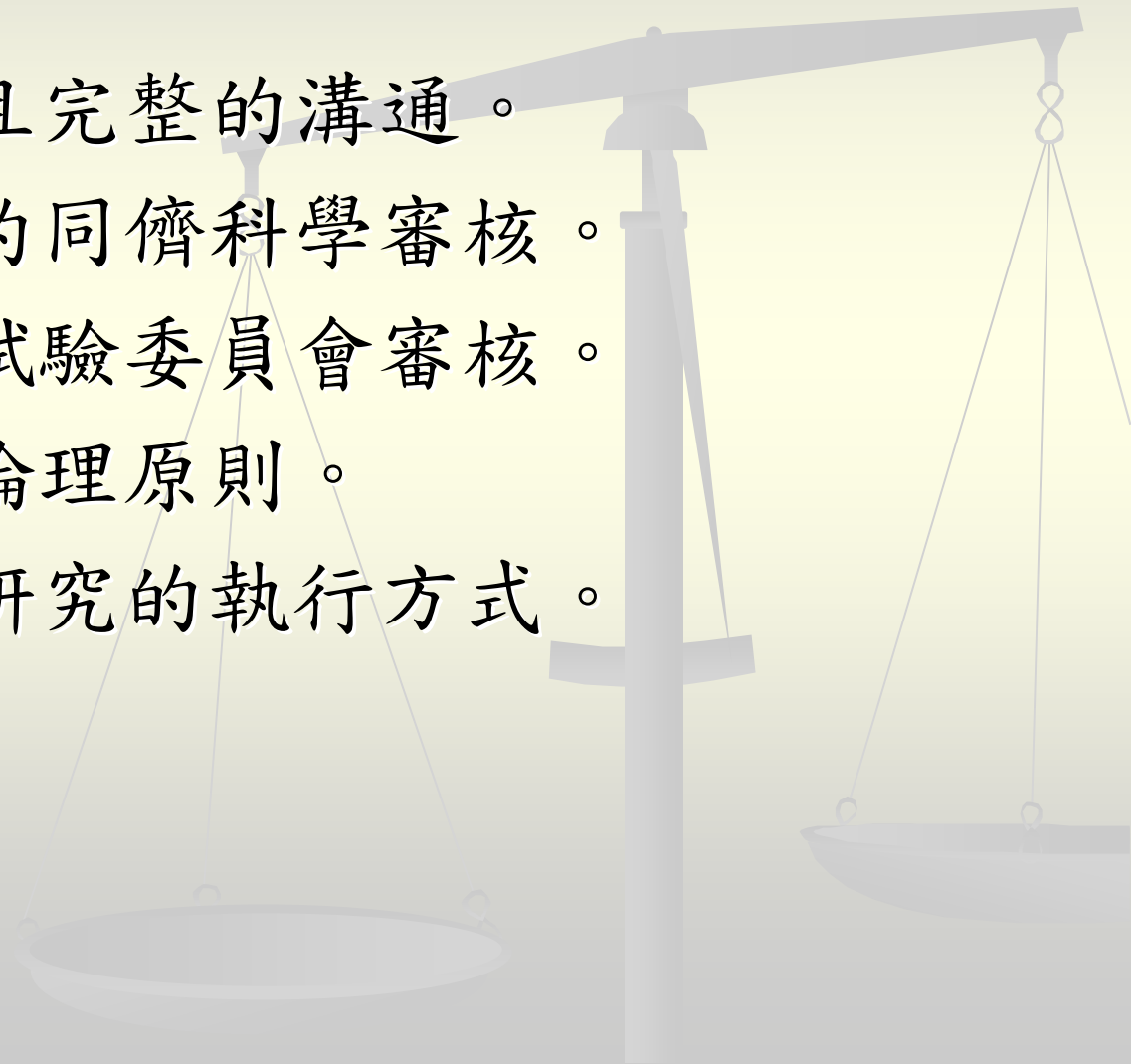
- 監督研究中人權的保護。
- 人體試驗委員會成員應該包含員工代表。

研究計畫包括下列的過程：

- 有一個符合科學原則的計畫案，並有一個紀錄資料的方法。
- 有主題，假設，以及目的。
- 考慮當地特色的溝通方法，並與當地社區及參與者保持溝通。
- 經由人體試驗委員會評審通過。


完整的研究計畫

- 精確且完整的溝通。
- 適當的同儕科學審核。
- 人體試驗委員會審核。
- 遵照倫理原則。
- 注意研究的執行方式。



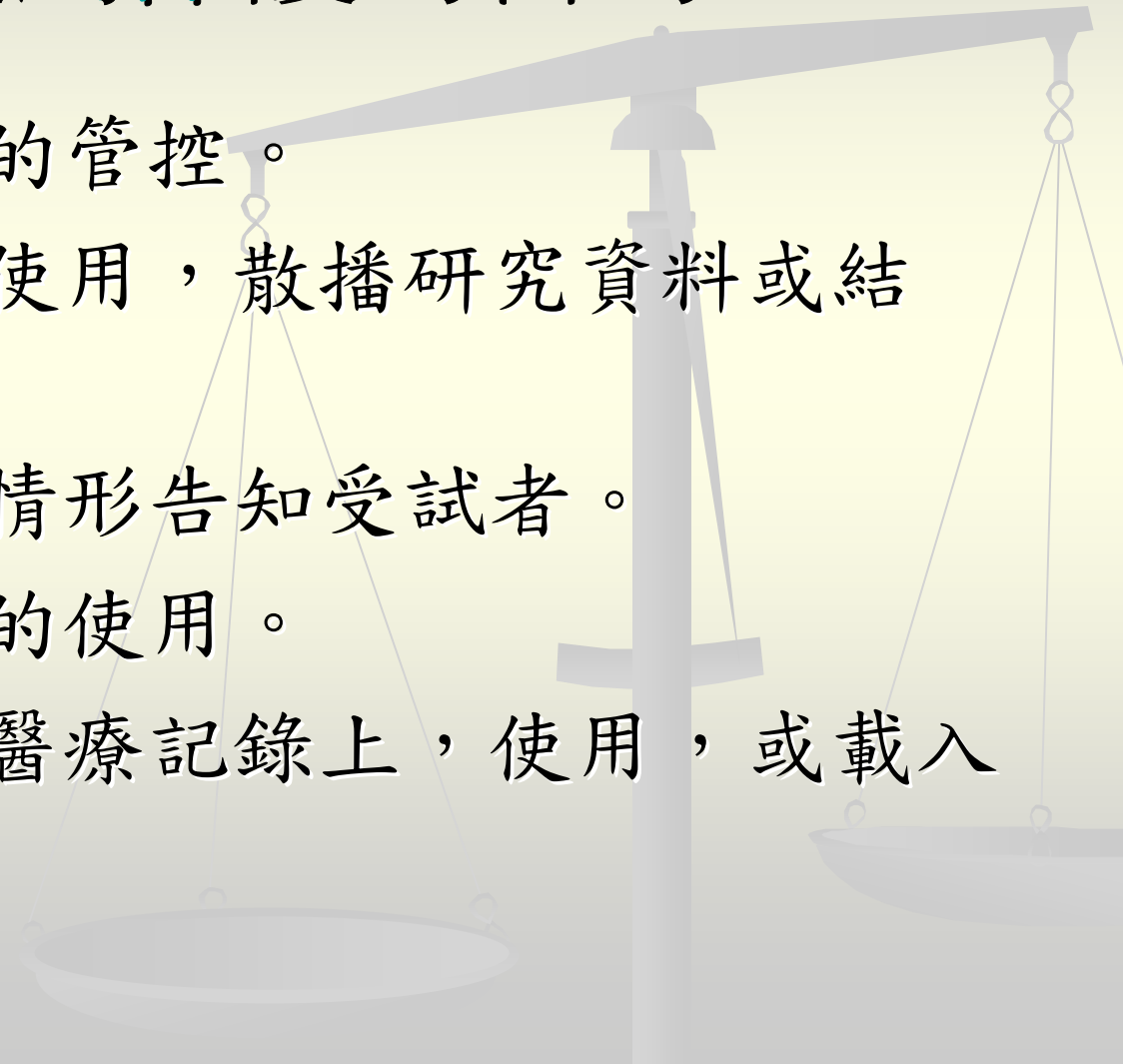
『薪水弱勢族群』議題

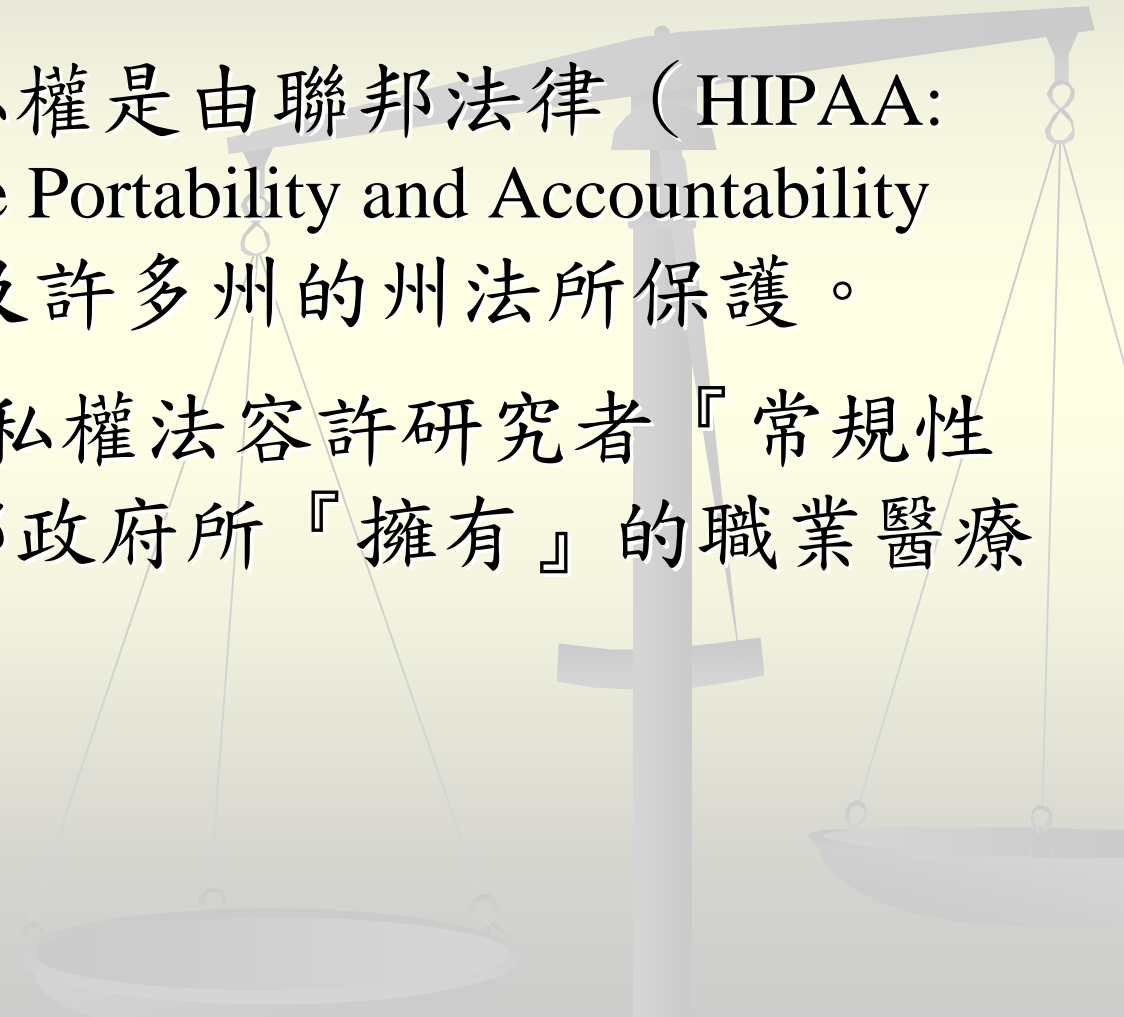
- 所謂『研究』的模糊定義 (45 CFR 46.102(d)).。
- 員工與雇主所聘僱的醫師之間的關係（類似臨床醫師與臨床研究者身份的衝突）
- 藉著『好處』來推廣參與研究的意願。
- 上級主管或研究主持人出面向員工索討身體標本作實驗。
- 機構對於一個員工的人事與職業健康資料的所有權。



希波克拉提斯誓言中強調的
“隱私權”是關於員工研究
的重要議題！

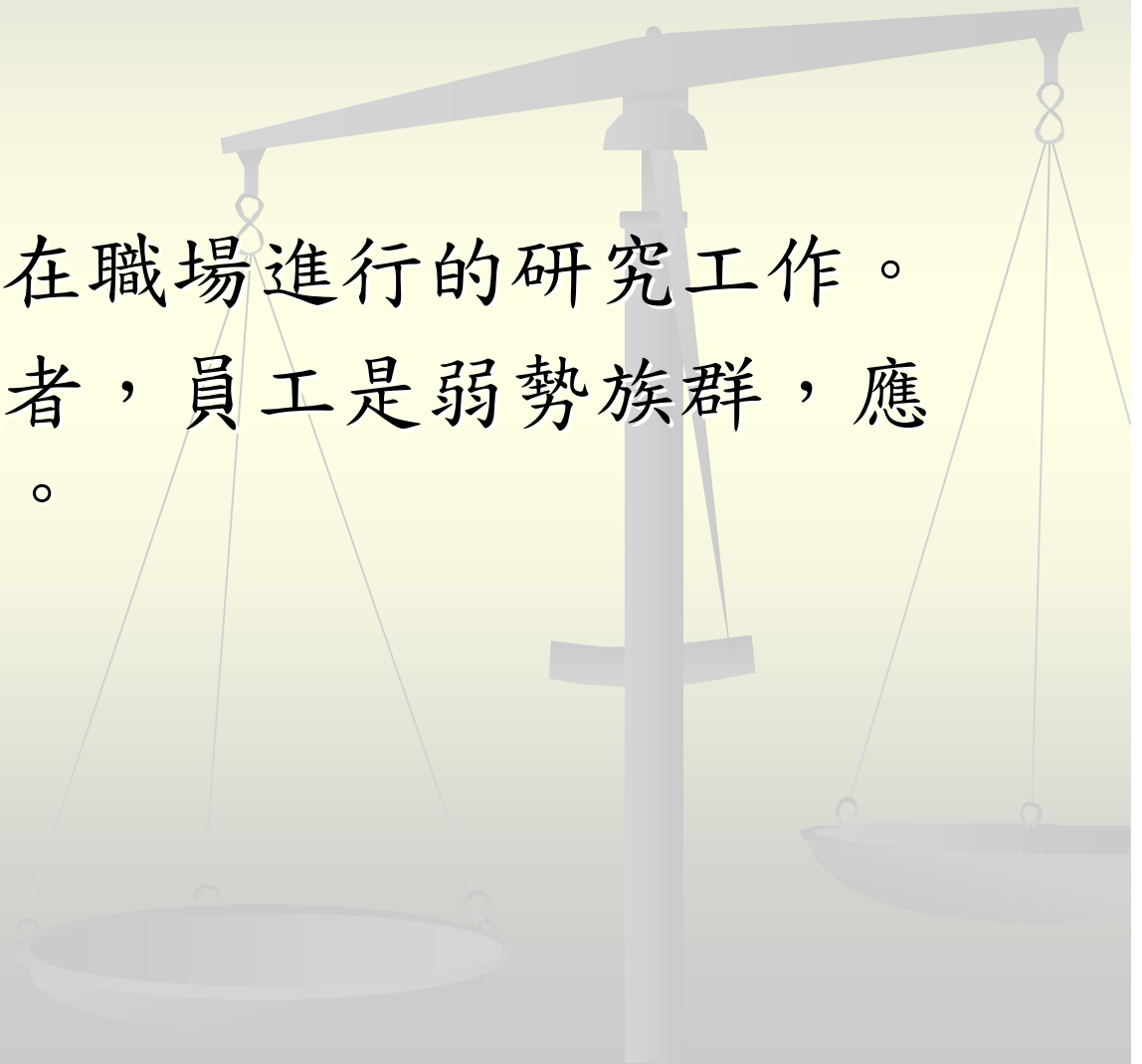
對於研究資料與記錄 若要達到保護的目的

- 收集到的資料的管控。
 - 誰可以拿到，使用，散播研究資料或結果？
 - 將上述的使用情形告知受試者。
 - 個人身份資料的使用。
 - 在員工人事或醫療記錄上，使用，或載入研究結果。
- 

- 
- 在美國，隱私權是由聯邦法律（HIPAA: Health Insurance Portability and Accountability Act 1996）以及許多州的州法所保護。
 - 1974 年的隱私權法容許研究者『常規性的』使用聯邦政府所『擁有』的職業醫療紀錄。

Summary 總結

- 一般法則適用於在職場進行的研究工作。
- 以員工作為受試者，員工是弱勢族群，應該更加小心保護。

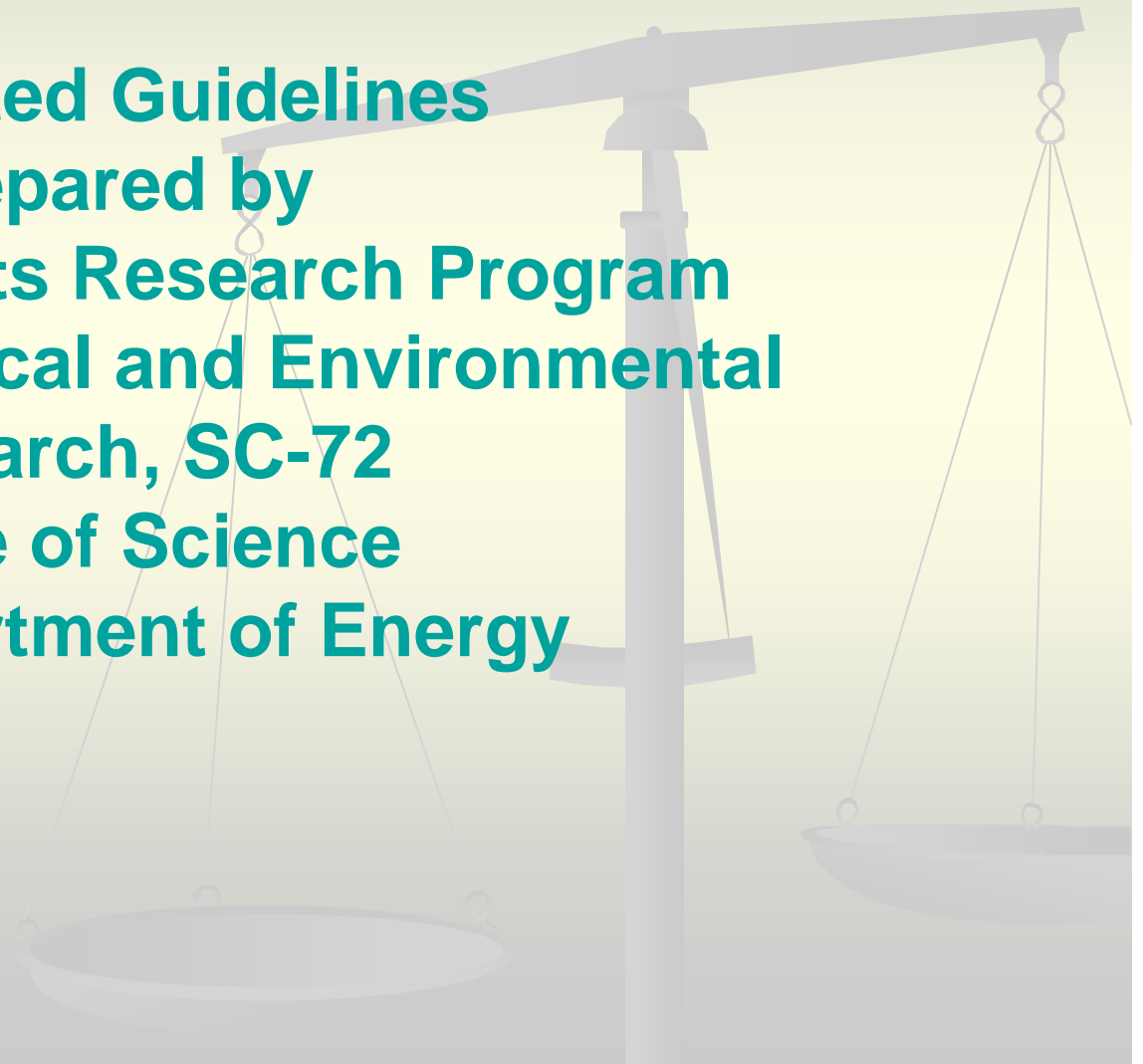


Creating an Ethical Framework for Studies That Involve the Worker Community

Suggested Guidelines

Prepared by

**Human Subjects Research Program
Office of Biological and Environmental
Research, SC-72
Office of Science
U.S. Department of Energy**



CHAPTER 1

THE NEED TO PROTECT WORKERS AS HUMAN RESEARCH SUBJECTS

Key Points:

- When workers are the subjects of research, the design of the study must assure that the rights and welfare of subjects are protected.
- Projects with workers as subjects are considered “research” when the *intent* of the study is for the information to be used for purposes beyond health monitoring and care of the individual.
- The unique vulnerabilities of workers who are research subjects include the threat or possibility of coercion; potential effects on job retention, job advancement, and insurability; and possible loss of personal and family privacy.

CHAPTER 2

FOUNDATIONS OF AN ETHICAL FRAMEWORK

Key Points:

- **The rights and welfare of workers are protected when everyone involved in worker studies understands and applies the Common Rule and the ethical principles of beneficence, justice, and respect for persons as described in The Belmont Report and many professional codes of ethics.**
- **It is expected that workers who are asked to participate in a study must not face coercion or reprisal for their decision to participate, not to participate, or to withdraw from a study. In the informed consent process, they must receive adequate and understandable descriptions of the study purpose, what is expected of them, why they were selected, and any benefits and risks they may experience if they choose to participate.**
- **All worker studies should undergo local review by an Institutional Review Board familiar with both the work force and the workplace.**

CHAPTER 3

THE CHALLENGE OF GENETIC INFORMATION IN WORKER STUDIES

Key Points:

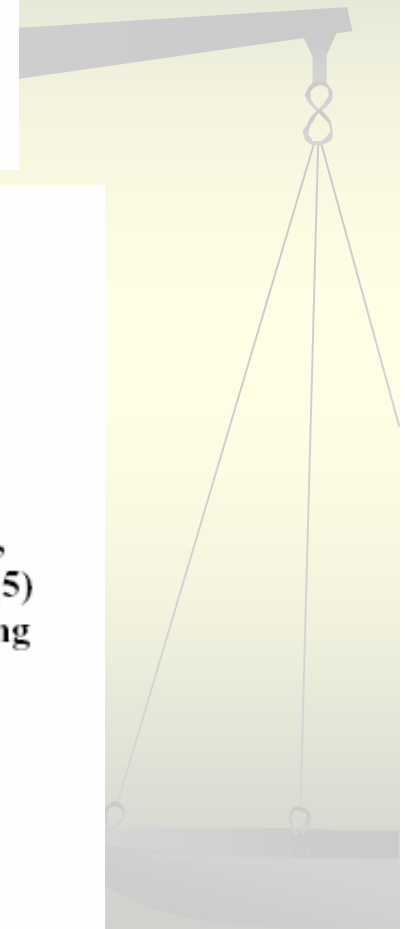
- **Genetic information gathered—intentionally or unintentionally—through worker studies presents unique challenges because it may reveal genetic information about a potential disease or other trait not yet expressed that could have significantly harmful consequences on the subject's future employability, insurability, and/or socio-economic status.**
- **A challenge specific to the use of tissue samples is that DNA is, at least in theory, a unique individual identifier and could be used to identify the donor.**
- **Genetic testing or screening should never be mandatory, especially in the workplace. Ideally, when genetic screening or testing is to be carried out, counseling is essential if the test results may entail choices or economic consequences for the person tested and his or her family.**

CHAPTER 4

PRIVACY, CONFIDENTIALITY, AND PROTECTION OF PERSONAL INFORMATION

Key Points:

- Protecting the privacy of human research subjects and confidentiality of information acquired about them in the course of research is particularly important in worker studies because of the possible personal or economic damage to the worker that can result from the release of confidential data.
- Proper management of study data must consider the: (1) use of data by others, (2) sharing of data, (3) use of personal identifiers, (4) use of pre-existing data, (5) appropriate dissemination of data and results, and (6) worker's rights regarding personal data and results. The data management plan must be part of the research plan approved by the IRB and should be disclosed when obtaining informed consent.
- The collection and use of genetic information, human tissues, and biological samples exposes subjects to individual risks from the acquisition and use of confidential data about them and their families. These risks create an additional set of complex ethical concerns that require the awareness of all stakeholders.



CHAPTER 5

STAKEHOLDERS: THEIR INTERESTS, CONCERNS, AND RESPONSIBILITIES

Key Points:

- Each worker study involves multiple stakeholders in addition to the researcher and worker.
- Stakeholders' interests in worker studies, both shared as well as conflicting concerns, that must be identified, discussed, and resolved.
- Stakeholders' *knowledge and acceptance of responsibilities* and their active participation in the worker-study process are essential to protecting the rights and welfare of workers as research subjects.

Workers

Employers

Unions

Researchers

Researchers' Institution

Agency Funding the Research

Institutional Review Boards

Public and Community

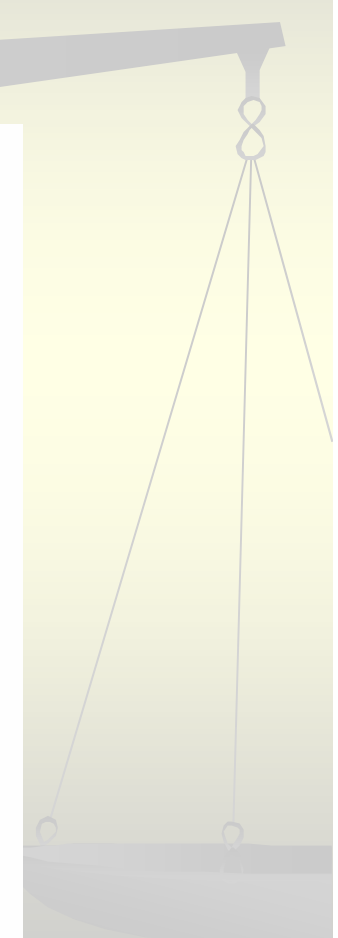
Government (Federal, State, and Local)

CHAPTER 6

IN CONCLUSION: PLANNING AND CONDUCTING ETHICAL WORKER STUDIES

Key Points:

- **Ethical considerations unique to worker studies must be addressed from planning through publication of the results. These considerations include the need for early notification of the purpose of the study, obtaining a fully informed consent, timely feedback of interim and final study results, and supporting each worker's freedom of choice to participate, not participate, or withdraw from the study.**
- **The protection of the worker-subjects and the success of the project depend upon a collaborative relationship established early in the design and development of a project with the involvement of the workers, the researchers, the employers, the unions, the community, and other stakeholders.**
- **Communication and coordination of all local worker health studies through an information "clearinghouse" at the local or agency level may be a good mechanism to improve coordination and success of worker studies. It would reduce duplication and multiple requests for individual workers to participate in similar studies, and could alleviate worker and community concerns by providing educational and comprehensive information.**



APPENDIX B

THE NIOSH APPROACH TO WORKPLACE STUDIES

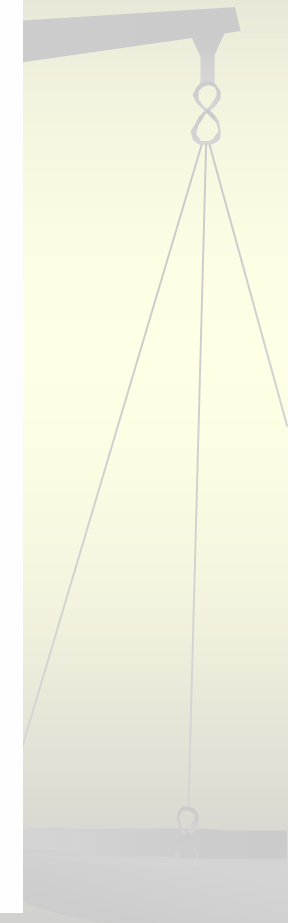
Michael Colligan, NIOSH

What is NIOSH?

The National Institute for Occupational Safety and Health (NIOSH) was established by the Occupational Safety and Health Act of 1970. NIOSH is part of the Centers for Disease Control and Prevention (CDC) and is the only federal agency whose sole mission is to conduct research and make recommendations for the prevention of work-related illnesses and injuries. NIOSH's responsibilities include:

- Investigating potentially hazardous working conditions as requested by employers or employees.
- Evaluating hazards in the workplace, ranging from chemicals to machinery.
- Creating and disseminating methods for preventing disease, injury, and disability.
- Conducting research and providing scientifically valid recommendations for protecting workers.
- Providing education and training to individuals preparing for or actively working in the field of occupational safety and health.

Although NIOSH and the Occupational Safety and Health Administration (OSHA) were created by the same Act of Congress, they are two distinct agencies with separate responsibilities. OSHA, a regulatory agency under the Department of Labor, is responsible for establishing and enforcing workplace safety and health regulations. NIOSH was placed under the Department of Health and Human Services (HHS) and was given the responsibility of conducting research, consultation, and training related to occupational safety and health. NIOSH is, therefore, engaged in both public health research and practice.



Thank you!

彰化基督教醫院 陳 明醫師

