

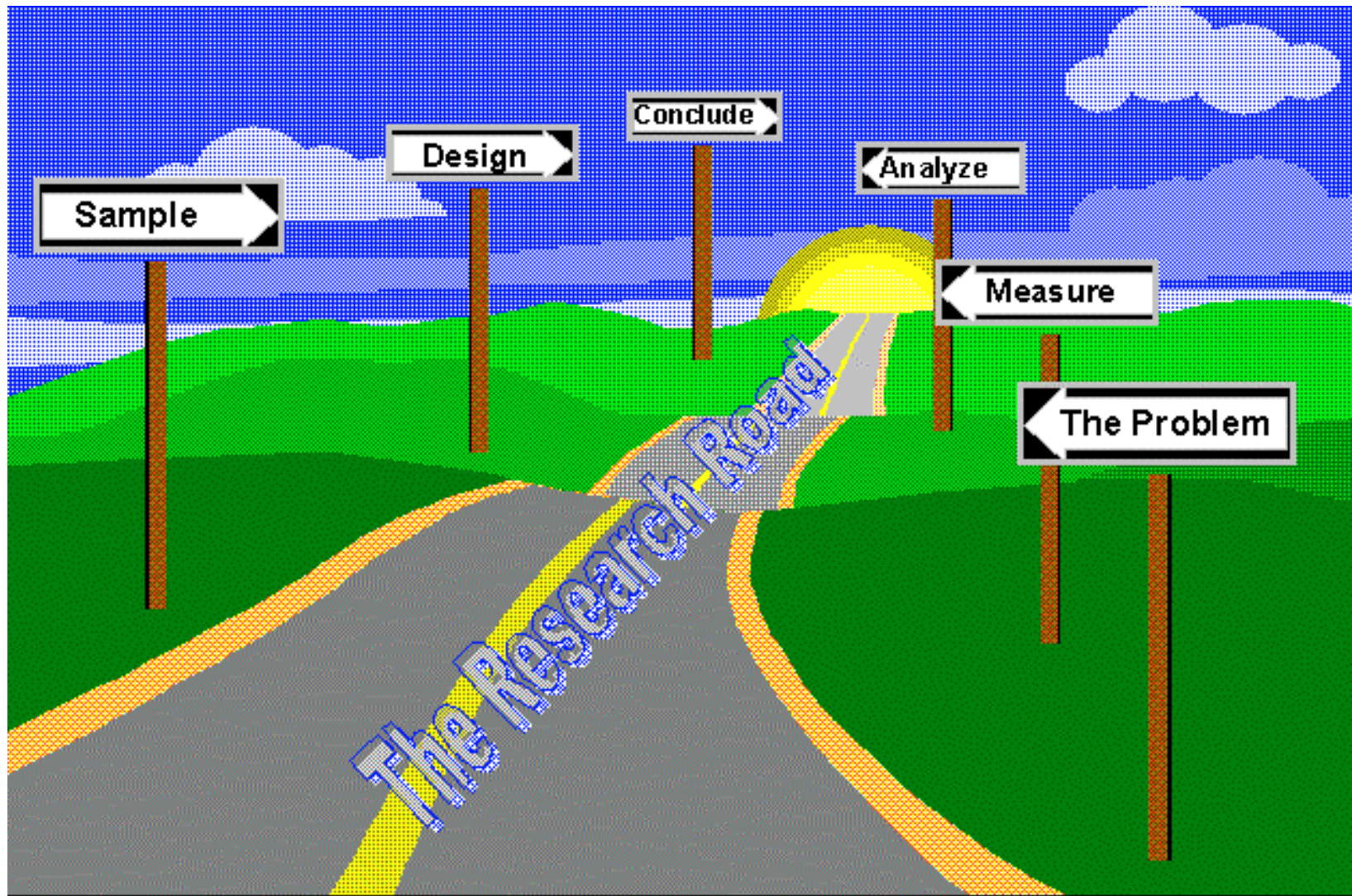
**"Well begun is half done"**

**Aristotle, quoting an old proverb**

## Important of human resource in science and technology development

Country	Investment in R&D (%GDP)	Number of researcher per 10,000 population (year 2003)	Number of patent (ave. for 1999-2001)	Competitiveness ranking for 60 countries		GDP per person (US\$ in 2001)
				all areas	Science and Technology	
USA	2.72	37	85,528	1	1	35,277
Germany	2.50	58	18,318	21	3	25,488
<b>Japan</b>	<b>3.07</b>	<b>70</b>	<b>118,535</b>	<b>23</b>	<b>2</b>	<b>37,950</b>
<b>Singapore</b>	<b>2.15</b>	<b>52</b>	<b>110</b>	<b>2</b>	<b>18</b>	<b>24,664</b>
Korea	2.53	40	29,363	35	19	9,628
Taiwan	2.30	51	24,700	12	8	14,216
Malaysia	0.71	5	27	16	42	3,531
China	1.23	8	4,989	24	22	840
<b>Thailand</b>	<b>0.26</b>	<b>2-5</b>	<b>98</b>	<b>29</b>	<b>55</b>	<b>1,921</b>
Philippines	0.08	2	6	32	58	692

Source: IMD World Competitiveness Yearbook 2004



# Research Ethics Framework

## POLICY GUIDELINES

The importance of the REF

The meaning of research

Governance, Ethics and Ethical Principles

'Research' is defined as any form of disciplined inquiry that aims to contribute to a body of knowledge or theory.

'Research ethics' refers to the moral principles guiding research, from its inception through to completion and publication of results and beyond - for example, the curation of data and physical samples after the research has been published.

## A 'Research Ethics Committee' (REC)

is defined as a multidisciplinary, independent, body charged with reviewing research involving human participants to ensure that their dignity, rights and welfare are protected.

The independence of a REC is founded on its membership, on strict rules regarding conflict of interests, and on regular monitoring of and accountability for its decisions.

## 'Human participants' (or subjects)

are defined as including

- *living human beings,*
- *human beings who have recently died (cadavers, human remains and body parts),*
- *embryos and fetuses,*
- *human tissue and bodily fluids, and*
- *human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).*

## GOVERNANCE, ETHICS AND ETHICAL PRINCIPLES

The distinction between *ethics* and *research governance*

Statement of the principles of *ethical research*

## Summary

- Researchers and research organisations should ensure that ***appropriate governance procedures and mechanism are in place*** to oversee social science research
- The ethical principles of **integrity, honesty, confidentiality, voluntary participation, impartiality** and the **avoidance of personal risk** to individuals or social groups characterize social science research that ***is conducted in a professional and ethical manner***
- The key concept of ***informed consent needs to be understood*** by both researchers and RECs in light of the context aims and objectives of the research and may require ongoing review and advice from fellow professionals or a REC itself.

# Language Of Research

(jargon people use)

types of questions

time in research

types of relationships

variable, hypothesis, data, and unit of analysis.

fallacies

# Ethics in Research

## Ethical Issues

*voluntary participation*

*informed consent*

*confidentiality*

*anonymity*

*right to service*

*Institutional Review Board (IRB)*

# International Guidelines

- Nuremberg Code
- Declaration of Helsinki
- Council for International Organizations of Medical Sciences (CIOMS)
- International Conference on Harmonization "Guideline for Good Clinical Practice"(ICH/GCP)
- WHO guidelines

# The Declaration of Helsinki

- The **Declaration of Helsinki** was developed by the World Medical Association (WMA), as a set of ethical principles for the medical in 1964 community regarding human experimentation.
- It is widely regarded as the cornerstone document of human research ethics
- Although it is not a legally binding instrument in international law

# Who cares ?

The Declaration of Helsinki

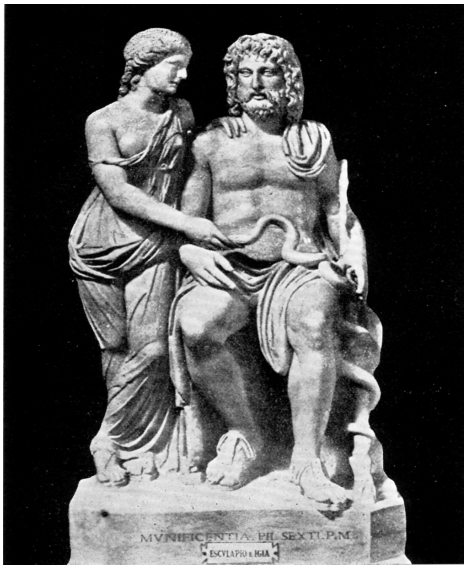
and

'The Role of Physicians'

# To care for and protect the Research 'Subject'

- Review some Codes of Practice
- Identify the underlying Ethical principles
- Illustrate how they are applied in the Declaration of Helsinki
- Discuss the specific role and responsibilities of the Physician Researcher

# Protection of the Human Subject in Medical Research



Cultural Morales

Laws respecting Human Rights

Consensus Guidelines

Professional Codes of Conduct

Individual Conscience

Research Ethics Committee (REC)

# The Medical Conscience

Conscientiousness is the readily identifiable mark of a good physician.

It reflects someone who is *'habitually governed by a sense of duty'* .

# The Medical Conscience

This conscience is the personal internal conviction

- which recognises the moral quality of one's motives and actions in order to apply
- what is right and correct
- what is wrong.

# The Medical Conscience

It is this 'internal' governance  
that is key to the trust patients continue  
to place in the medical profession worldwide  
irrespective of the system of healthcare.

# Seven Ethical Pillars of Clinical Research

Autonomy

Beneficence

Justice

Confidentiality

Fidelity

Truthfulness

Non malfeasance

# Declaration of Helsinki 1964



- Potential benefits must outweigh hazards
- The need for informed consent
- A distinction between Scientific and Clinical Research

## Declaration of Helsinki Revisions

1 <sup>st</sup>	1975	Tokyo
2 <sup>nd</sup>	1983	Venice
3 <sup>rd</sup>	1989	Hong Kong
4 <sup>th</sup>	1996	Somerset West. S. Africa
5 <sup>th</sup>	2000	Edinburgh

# Declaration of Helsinki

Para 22

'...after ensuring that the subjects has understood the information, the physician should then obtain the subjects freely-given informed consent, preferably in writing....'

# Principles of the Declaration

The Declaration is morally binding on physicians

The obligation overrides any national or local laws or regulations, if the Declaration provides for a higher standard of protection of humans than the latter.

Investigators still have to abide by local legislation but will be held to the higher standard.

## Good Clinical Practice (GCP)

is an international quality standard

It also provides assurance of the safety and efficacy of the newly developed compounds.

GCP Guidelines include standards on how clinical trials should be conducted, *define the roles* and *responsibilities* of clinical trial sponsors, clinical research investigators, and monitors.

# แพทยสภา

## “คณะกรรมการด้านจริยธรรม”

คณะกรรมการที่สถาบัน องค์กร หรือหน่วยงานแต่งตั้งขึ้นเพื่อทำหน้าที่  
ที่ทบทวนพิจารณาด้านจริยธรรมของการศึกษาวิจัยและการทดลองใน  
มนุษย์ เพื่อคุ้มครองสิทธิ ความปลอดภัย และ ความเป็นอยู่ที่ดีของ  
อาสาสมัครในการศึกษาวิจัยและการทดลองในมนุษย์

# ข้อบังคับแพทยสภาว่าด้วยการรักษาจริยธรรมแห่งวิชาชีพเวชกรรม (ฉบับที่5) พ.ศ. 2544

## หมวดที่ 6 การศึกษาวิจัยและทดลองในมนุษย์

ข้อที่5 ผู้ประกอบวิชาชีพเวชกรรมผู้ทำการหรือร่วมทำการศึกษาวิจัย หรือ การทดลองในมนุษย์ สามารถทำการวิจัยได้เฉพาะเมื่อโครงการ ศึกษาวิจัยหรือการทดลองดังกล่าว ได้รับการพิจารณาเห็นชอบจาก คณะกรรมการด้านจริยธรรมที่เกี่ยวข้องแล้วเท่านั้น

ประกาศในราชกิจจานุเบกษา วันที่ 8 กุมภาพันธ์ 2544

บังคับใช้เมื่อพ้นกำหนด180วันนับแต่วันถัดจากวันประกาศ (1 สิงหาคม 2544)

# Social science research paradigms

- covering a wide range of disciplines and is often linked with the humanities, or more applied areas such as social policy
- involving human participants or subjects *directly* as the source of primary data, or *indirectly*
- using broad range of research techniques raising questions about the appropriate process of ethics review, and indeed the meaning of ethics itself
- interdisciplinarity in nature requires greater dialogue between fields, and this should foster shared learning and a predisposition towards greater reflexivity in the determination of ethical judgement
- a strong commitment to qualitative research
- **assessment of 'risk'** - in terms of its dimensions, hierarchy and prioritization - needs to be informed by these deliberations

### CASE STUDY 1:

Homelessness, begging and drug use

### CASE STUDY 2:

Enhancing the independence of older people with dementia in residential care

### CASE STUDY 3:

Teachers' views on the impact of league tables

### CASE EXAMPLE 4:

Clinical trial of stem cell therapy

### CASE EXAMPLE 5:

International study of health related quality of life

# TRUST

Science has become

- so complex and
- closely intertwined with society's needs

## ETHICS and RESPONSIBILITIES

Research Supervisors and Mentors

Formal introduction

# THE SOCIAL FOUNDATIONS OF SCIENCE

Scientific progress and changes in the relationship between science and society are creating new challenges for the scientific community.

The conduct of research is more closely monitored and regulated than it was in the past.

The part played by science in society has become more prominent and more complex, with consequences that are both invigorating and stressful.

# THE SOCIAL FOUNDATIONS OF SCIENCE

EXPERIMENTAL TECHNIQUES AND THE TREATMENT OF DATA

THE SELECTION OF DATA

VALUES IN SCIENCE

CONFLICTS OF INTEREST

INDUSTRIAL SPONSORSHIP OF ACADEMIC RESEARCH

PUBLICATION AND OPENNESS

THE ALLOCATION OF CREDIT

ERROR AND NEGLIGENCE IN SCIENCE

MISCONDUCT IN SCIENCE

FABRICATION IN A GRANT APPLICATION

**PLAGIARISM**

# PLAGIARISM

## What is it?

to steal and pass off (the ideas or words of another) as one's own

to use (another's production) without crediting the source

to present as new and original an idea or product derived from an existing source.

to commit literary theft

In other words, plagiarism is an act of fraud. It involves both stealing someone else's work and lying about it afterward.

## All of the following are considered plagiarism:

- turning in someone else's work as your own
- copying words or ideas from someone else without giving credit
- failing to put a quotation in "quotation marks"
- giving incorrect information about the source of a quotation
- changing words but copying the sentence structure of a source without giving credit
- copying so many words or ideas from a source that it makes up the majority of your work, whether you give credit or not

# Why Students Plagiarize?

There are many reasons students plagiarize.

- 1 Sometimes **deadlines** come around more quickly than expected,
2. Sometimes **assignments** feel overwhelming, and
3. Sometimes the boundaries of plagiarism and research just get confused.

What situations are most likely to result in plagiarism?

How can they be avoided?

Learning to identify the factors that make plagiarism an attractive alternative is the best way to stop it before it starts.

# Concept Mapping

