



Ministry of Health and Sports

# **An overview of Responsible Conduct of Research : Shared Values, Policies, Regulations and Responsibility**

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# Disclaimer

Note that this is a general slide presentation designed for a broad audience of clinical researchers.

Accordingly, some sections may not be applicable for all studies.

# Acknowledgements

The presentation is based on ORI Introduction to Responsible Conduct of Research by Nicholas H. Steneck

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# What is Research? “Rechercher”

“diligent and systematic inquiry or (scientific) **investigation** into a subject in order to discover or revise facts, theories, applications, etc.”

[Webster's Encyclopedic Unabridged Dictionary]

“(scientific) **investigation** undertaken in order to discover new facts, get additional information, etc.”

[The Advanced Learner's Dictionary of Current English 2<sup>nd</sup> Edition]

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# Responsible Conduct of Research (RCR) - 30 years ago

## THE RESPONSIBLE CONDUCT OF RESEARCH IN THE HEALTH SCIENCES

Report of a Study by a  
Committee on the Responsible Conduct of Research  
INSTITUTE OF MEDICINE  
Division of Health Sciences Policy

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# **Responsible Conduct of Research (RCR)**

## **- 30 years ago**

“The importance of formal RCR education was first explicitly recognized in the 1989 Institute of Medicine Report “The Responsible Conduct of Research in the Health Science”.

**[National Institutes of Health]**

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# What is RCR ?

“The pursuit of scientific investigation with integrity”

**[National Institutes of Health]**

- “**integrity**” means firm adherence to a code, moral values-standards, incorruptible
- It involves the awareness and application of established **professional norms and ethical principles** in the performance of **all activities** related to scientific research

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# Research Integrity is important to -

## A. Researchers

- Researchers rely on **trustworthy results of other researchers** to make scientific progress
- Researchers rely on **public support**, whether through public investments or their voluntary participants in experiments

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# Research Integrity is important to -

## B. Public

- The Public rely on scientific progress to better the lives of everyone

## C. Policy Makers

- The Policy Makers rely on researchers for decision-making

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# RCR - Objectives

- To practice high standards of ethics and accountability in such step of research process, from planning to publication and utilization of research findings or practicing research integrity.
- To achieve research integrity (adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms).

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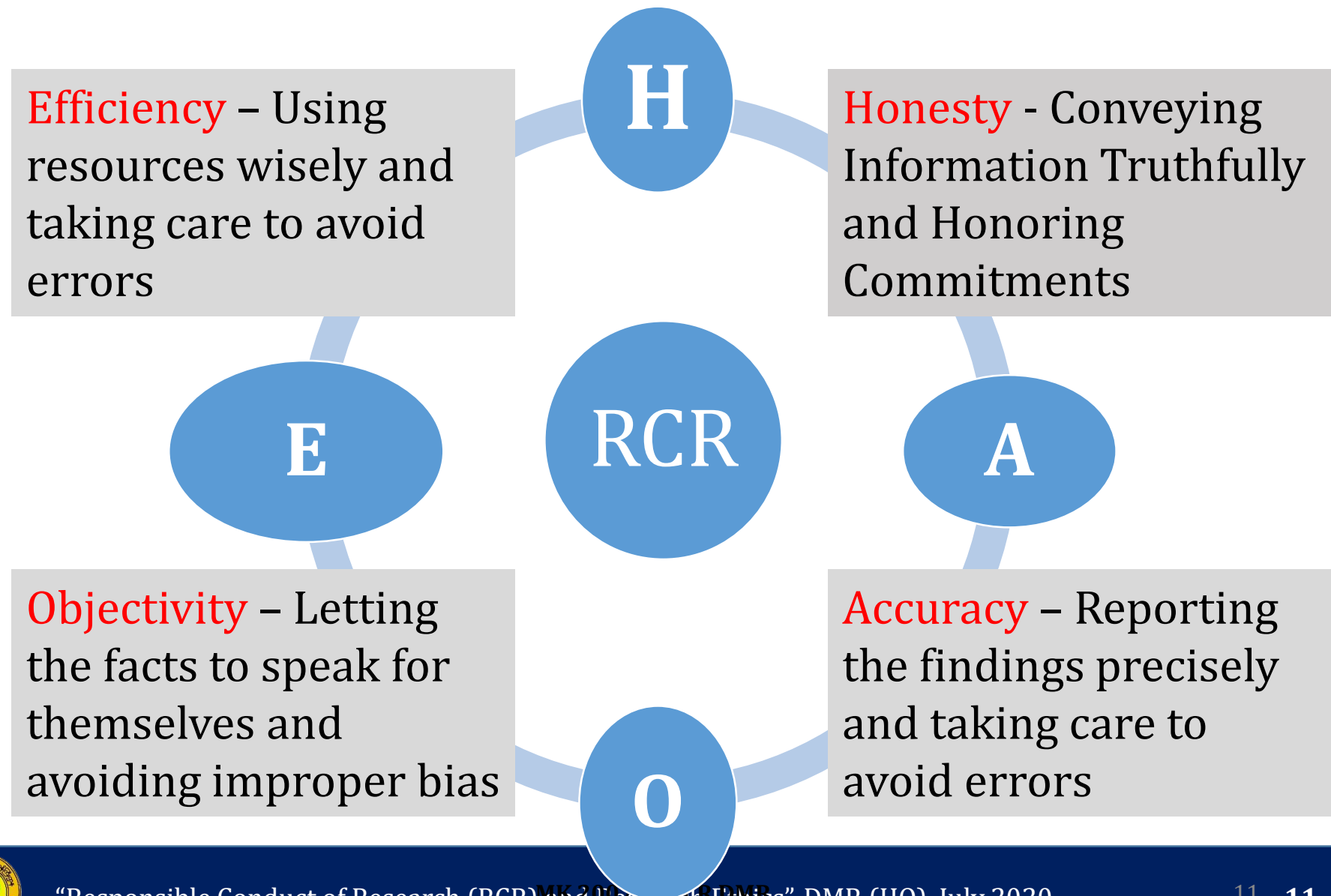
# Which way is the Best Way to undertake RCR?

- There is **no universal method** that applies to all scientific investigations.
- Accepted practices for the responsible conduct of research **can and do** vary from discipline to discipline and even from laboratory to laboratory.

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# Four Building Blocks of RCR



# Who is involved with RCR?

- **Researcher** – A person responsible for honestly, accurately, efficiently, and objectively conduct the research process.
- **Research Administrator** – Some role or responsibility for developing research integrity and compliance policies and procedures including educating researchers.

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1. Authorship and Publication
  2. Collaborative Research
  3. Conflicts of Interest
  4. Data management
  5. Environmental and Laboratory Safety
  6. Human Subjects Research
  7. Use and care of vertebrate animals
  8. Peer Review
  9. Research Misconduct
  10. Responsibilities of Mentors and Trainees
  11. Science and Engineering
- Core  
Areas of  
RCR**

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# Core Areas of RCR

Authorship and Publication	“Fabrication, Falsification, or Plagiarism” in proposing, performing, or reviewing research, or in reporting research results.
Collaborative Research	Responsible collaboration are defined by openness, communication and trust
Conflicts of Interest	When two or more competing interests create the perception or the reality of an increased risk or bias or poor judgement.
Data Acquisition, Management, Sharing and Ownership	The integrity of research depends on the integrity in all aspects of the collection, use, retention, and sharing of data.

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# Core Areas of RCR

## Environment and Laboratory Safety

Safety of all project personnel and the proper use and disposal of materials in a laboratory setting.

## Human Subjects Research

COI – where two or more competing interest create the perception or the reality of an increase risk of bias or poor judgment.

## Humane Use and Care of Vertebrate Animals in Research

Rules in this area ensure that research entails procedures that will cause the least pain and /or distress to the least amount of animals.

## Peer Review

Academic/scientific inquiry is relatively specialized, peers with similar expertise are in the best position to judge one another's work.

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# Core Areas of RCR

Research Misconduct	Human subject research is heavily regulated and based on the principles, respect for persons, beneficence, and justice.
Responsibilities of Mentors and Trainees	Authorship is the most visible form of credit and means for sharing and contributing to scientific knowledge.
Science and Engineering	It is vital that “the safety, health, and welfare of the public” is upheld in professional practice and in research activities. Especially important if a researcher has good reason to believe that the public might be harmed.

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# Policies (NIH)

- National Institutes of Health (NIH) requires all **trainees, fellows, participants, and scholars** receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant receive instruction in responsible conduct of research.

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# Policies (NSF)

- When a principal investigator (PI) receives a grant from the **National Science Foundation**, the PI will require students to complete the Collaborative Institutional Training Initiative (CITI) training module *before starting research on the project*.
- If **human subjects** are used in research, students will also need to take a course on Protecting Human Research Participants.
- If **animal subjects** are used in research, students will also need to take a course in Laboratory Animal Research.

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# Policies (MoHS)

- With the aim of **assuring** Responsible Conduct of Research, the Ministry of Health and Sports have formed Institutional Review Boards (IRB) to **appraise the research protocols** on the **ethical** issues, the **quality aspects** of methodology and the **applicability** to current health problems.
- The principal investigator (PI) must submit the research protocol to the **designated IRB for review**.
- The PI must **follow the instructions** as outlined by the respective IRB.
- The PI must conduct the research project only after receiving the **Ethical Clearance Certificate** from the respective IRB.

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# Regulations

- Regulation not only protects **participants in research** (human and animal), but it also protects **researchers**.
- It sets out clearly **what is acceptable and what is not**, and therefore provides a framework within which researchers work.

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# Self-regulation

Research is based on the same ethical values that apply in everyday life.

- Honesty
- Fairness
- Objectivity
- Openness
- Trustworthiness and
- Respect for others

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# Self-regulation

- Religion also has a role in the self-regulation
- The **five moral precepts** are the five principles that Buddhists follow in order to live ethically and morally good lives.
- **Similar teachings** are also present in other religions.

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# Professional self-regulation

- Researchers have an obligation to honor **the trust** that their colleagues place in them.
- Researchers have an obligation to **themselves**.
- Researchers have an obligation to act in ways that serve **the public**.

[On being a Scientist – Third Edition]

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# Professional self-regulation

- Each profession has its own ethical standards, which govern the practices in the profession.
- In medicine, physicians abide by rules such as “do no harm,” “promote the patient’s health,” “maintain confidentiality,” and “honor the patient’s right to make decisions”

*[Beauchamp and Childress 2001]*

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# Professional self-regulation

Myanmar Medical Council - some salient points

- To protect, promote and maintain the health and safety of patients
- To promote high standards of medical education and training
- To ensure the highest level of medical ethics

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# US Government Regulations

- 1966 Animal Welfare Act (PL 89-544),
- 1974 National Research Act (PL 93-348),
- 1985 Health Research Extension Act (PL 99-158).
- 1989, the Department of Health and Human Services (HHS) established the Office of Scientific Integrity (OSI) and the Office of Scientific Integrity Review (OSIR),
- 1992 The Office of Research Integrity (ORI)

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# The Responsibility of the IRBs

- To ensure the **highest level** of medical ethics
- To **protect, promote and maintain** the health and safety of patients
- To promote **high standards** of medical ethics education and training
- To **safeguard** Human Subjects by enforcing the Responsible Conduct of Research

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# Procedure (IRB-1 MoHS)

- **The PI shall follow the instructions** as outlined in the webpage of MOHS. (<https://mohs.gov.mm/page/2148>)
- **The PI must attend the IRB meeting** and must respond to the comments and queries by the IRB members and follow the decision of the IRB.
- **The PI should initiate the research project only after** receiving the Ethical Clearance Certificate from the IRB.
- Depending on the nature of the study, the **PI may need to complete the designated training module** on Protecting Human Research Participants and need a passing mark of 80% *before starting research on the project.*

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# Singapore Statement on Research Integrity

**Preamble.** The value and benefits of research are vitally dependent on the integrity of research. While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken.

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## PRINCIPLES

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**Honesty** in all aspects of research

**Accountability** in the conduct of research

**Professional courtesy and fairness** in working with others

**Good stewardship** of research on behalf of others

*Developed during Second World Conference on Research Integrity,  
21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research  
Posted 2010 September 22*

# Responsibilities

1. Integrity
2. Adherence to Regulations
3. Research Methods
4. Research Records
5. Research Findings
6. Authorship
7. Publication
8. Peer Review
9. Conflict of Interest
10. Public Communication
11. Reporting Irresponsible Research Practices
12. Responding to Irresponsible Research Practices
13. Research Environments
14. Societal Considerations

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# Resources

