Ensuring Responsible Conduct of Research:

Quality in Research
Research Ethics
Scientific Integrity
Research Integrity

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2022 (Detailed version)

Why do we do research?

Personal gratification i.e.

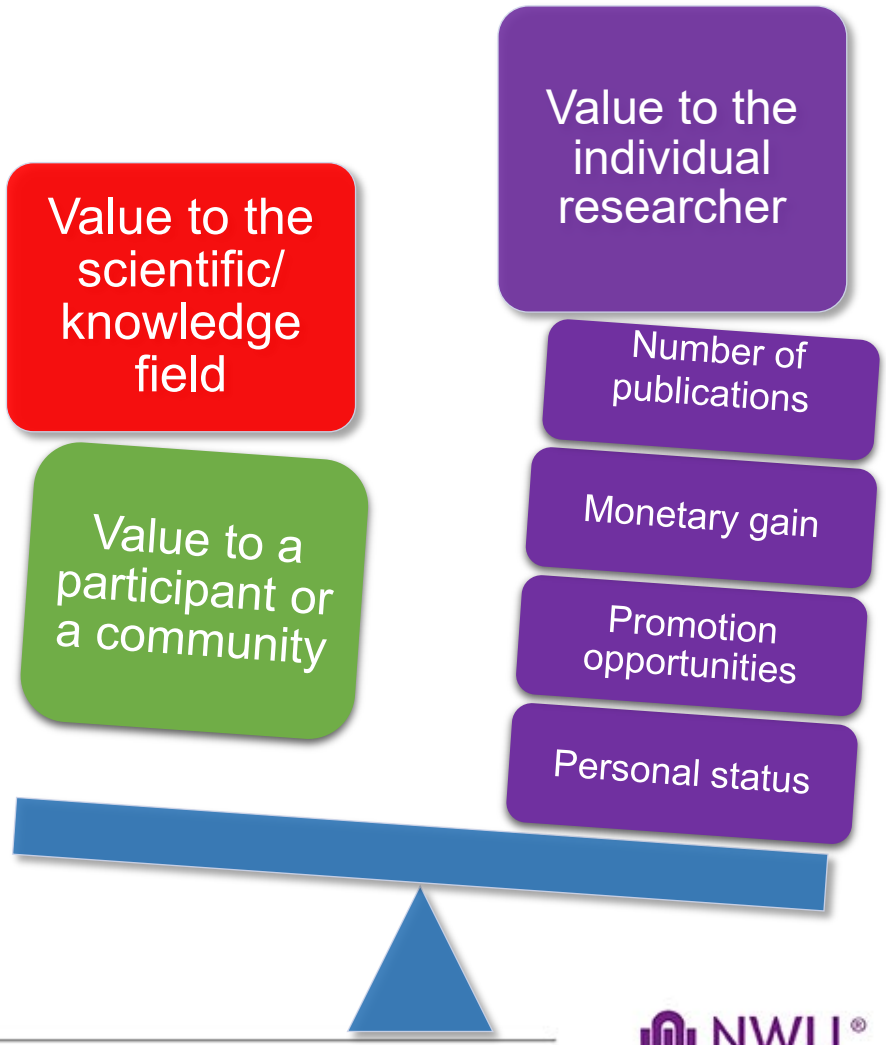
- Promotion
- Funding opportunities
- Subsidized funds for conference attendance etc.
- Research rating/benchmarking etc.

Interesting

Value to science

Value to participant/society

Unfortunately see an unhealthy tipping of the scale.



The greater scientific community can only **innovate** and **flourish** when:

- Its members function together as a body to ensure a climate that promotes confidence and trust in research findings.
- Encourages free and open exchange of research materials and new ideas.
- Upholds personal and institutional accountability.
- Acknowledges and respect the intellectual contributions of other in the greater scientific community (webGURU).

Honesty, Trust & Responsibility

Trust comes from **honesty**.

Honesty is central to the relationship between the:

* Researcher
* Participant
* Other interested parties.

Honesty and trust **lead to basic responsibilities** of the research community.

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Basic responsibilities of the research community

- To formulate the principles of research they will follow.
- To define the criteria for proper research behaviour.
- To maximise the quality and robustness of research.
- To respond adequately to threats to, or violations of, RI.

As indicates one of the responsibilities of a research community is:

Quality in Research

What do we have to look at to ensure quality?

1) Consensus among a community of scholars is one of the most respected means of quality assessment.

2) Research quality and evidence must be **assessed and deemed sufficient** prior to dissemination and knowledge utilization initiatives.

3) Consensus standards for assessment are needed to facilitate the knowledge translation process

(Technical brief of FOCUS).

4) Should have **value** to:

- The scientific community
- Society
- The researcher

So, what then is essential for all this to happen?

Research:

* Must be based on a set of ethical principles and follow the highest ethical norms and standards.

* Conducted in such a way that it speaks of Research Integrity/Responsible Conduct of Research (RCR).

This then brings us to the rest of my focus of my lecture today:

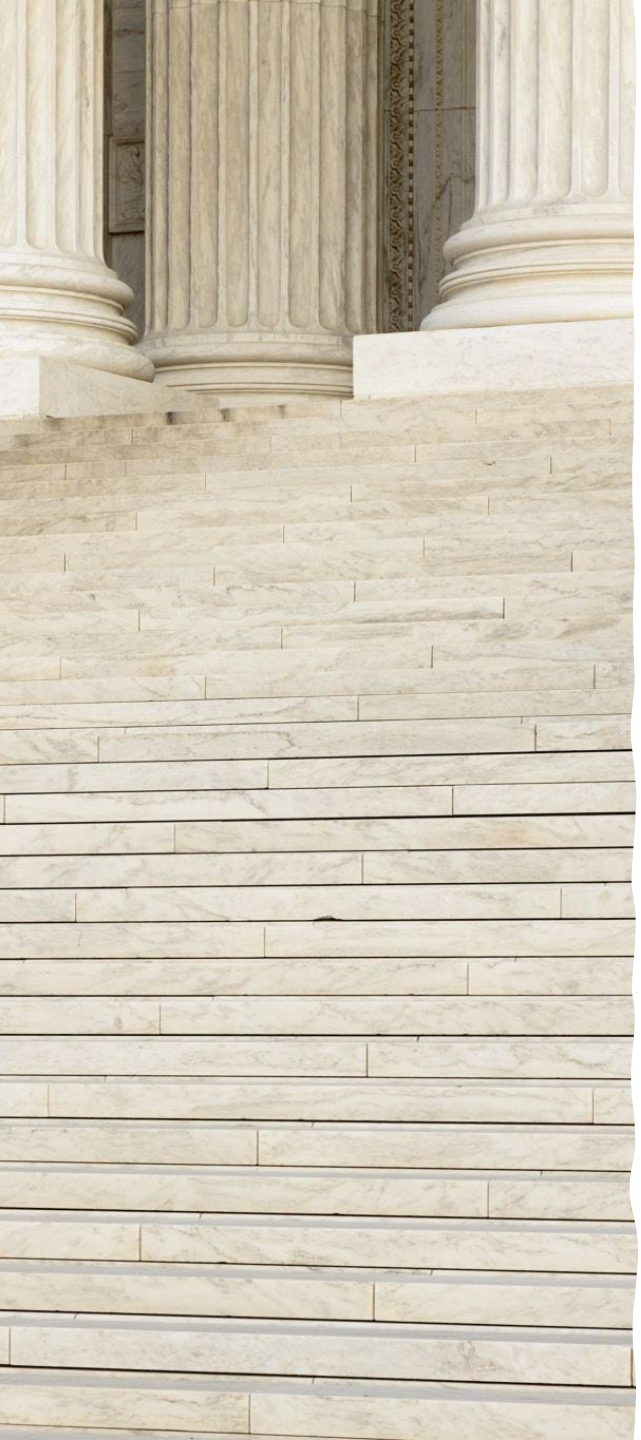
* Research ethics
* Research Integrity
* Scientific Integrity

(Not the same as research integrity)

Often these concepts are seen as the same or used interchangeably.

They are very different.

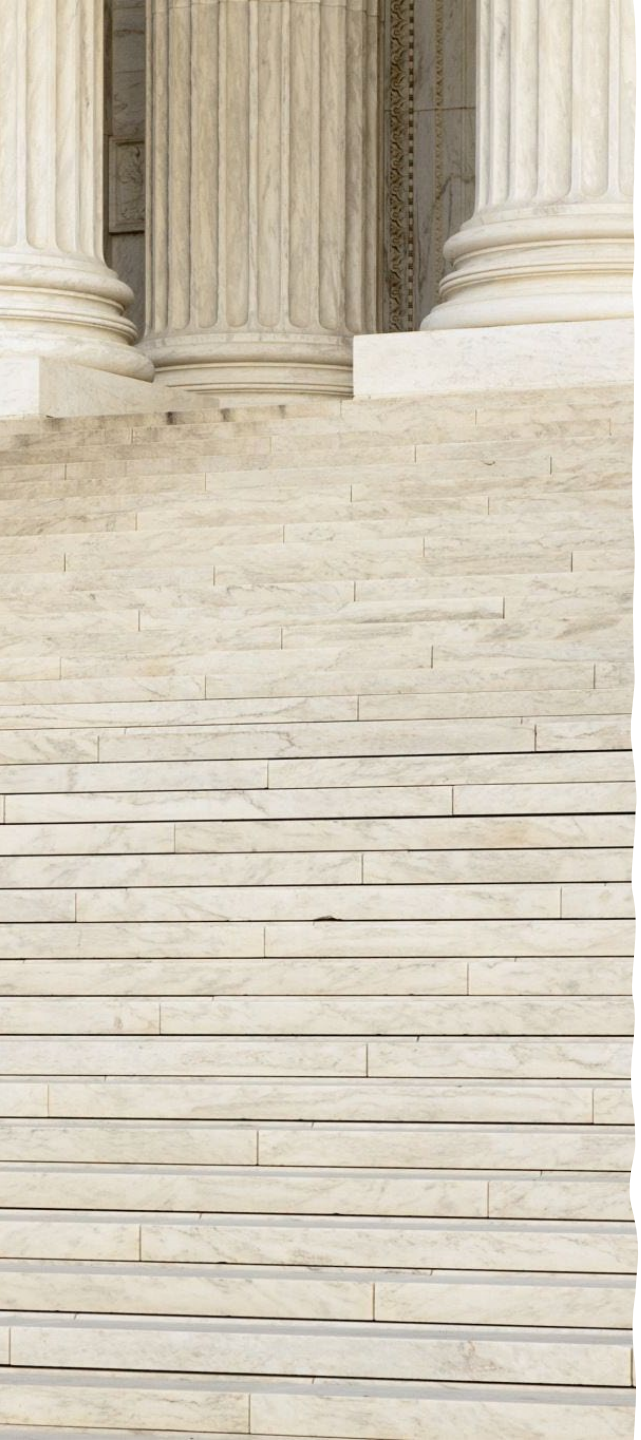
But are closely intertwined like the threads in a rope.



Ethics in its broader sense

Definition:

"*The study of morality – a careful and systematic reflection on and analysis of moral decisions and behaviour, whether past, present or future*" (Williams, 2009 for the World Medical Association).



Morality versus Ethics

Morality: the value dimension of human *decisions* and *behaviour.*

"*Doing the right thing*".

Ethics: about what we ought to do in a particular situation.

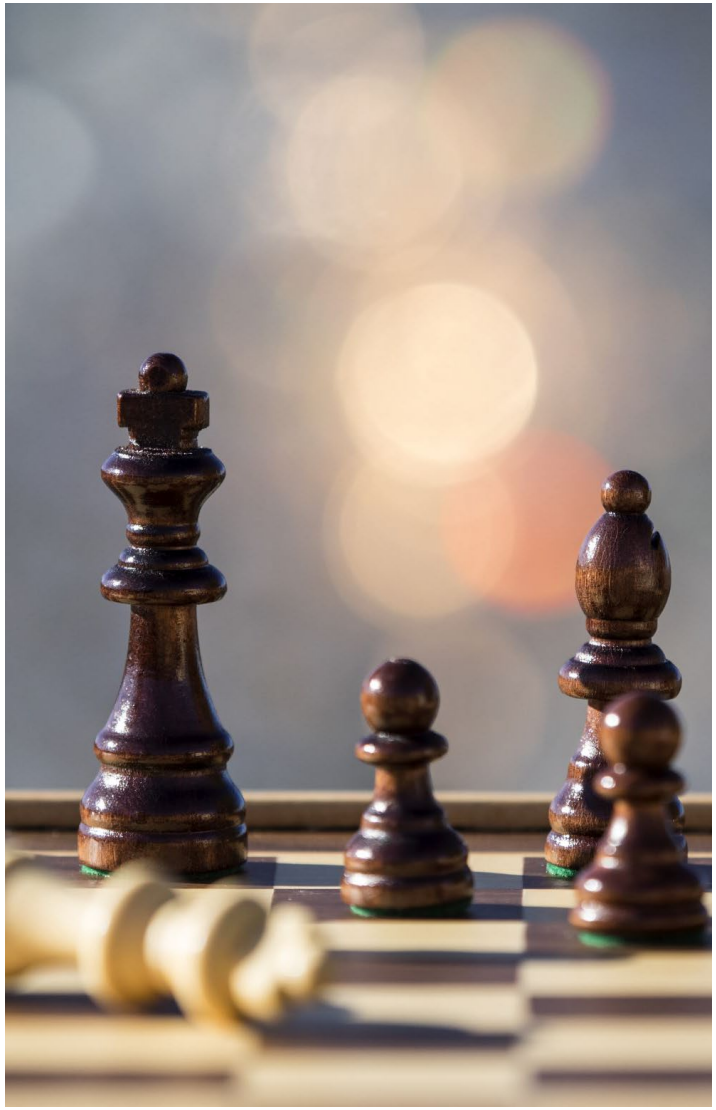
"*Knowing what the right thing is to do*".

Ethics is the philosophical discipline that reflects on the question of:

Good and Bad

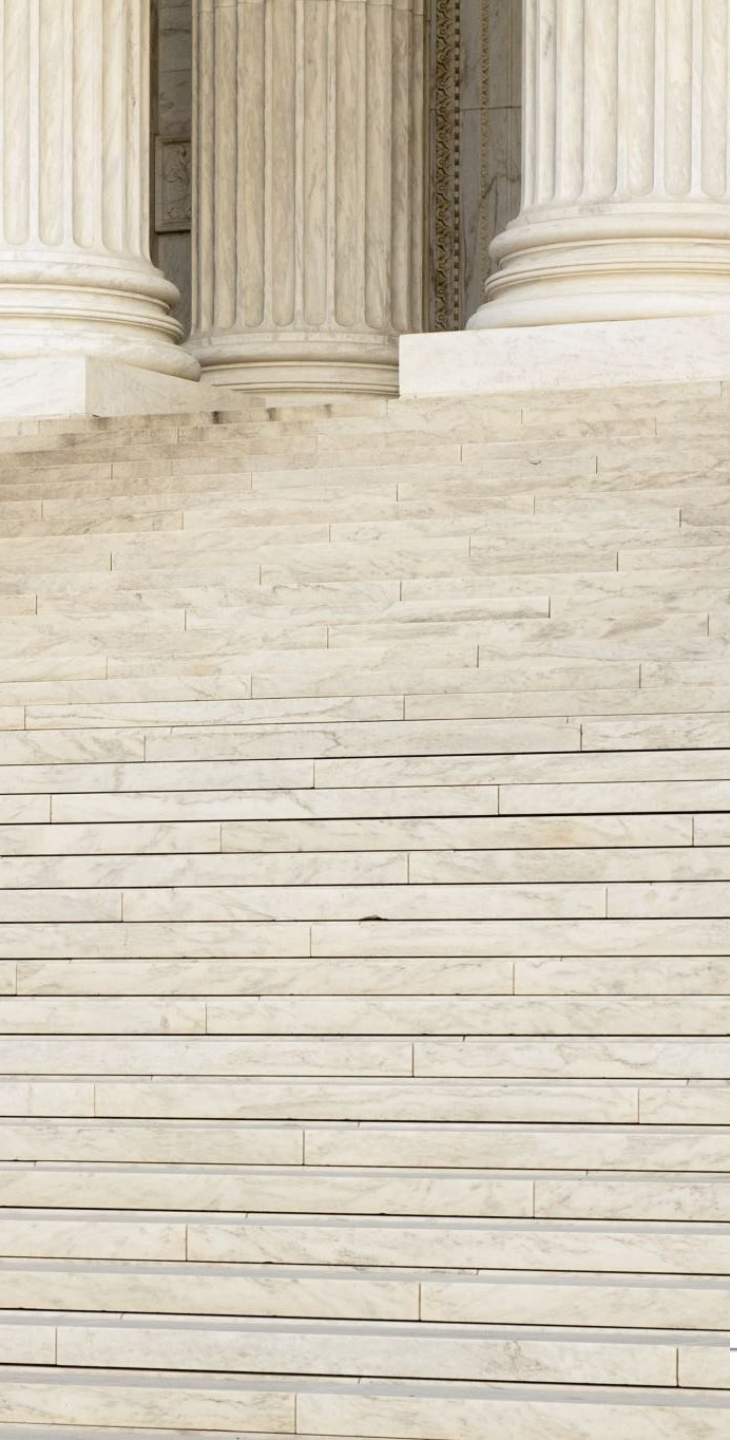
Or

Right or Wrong



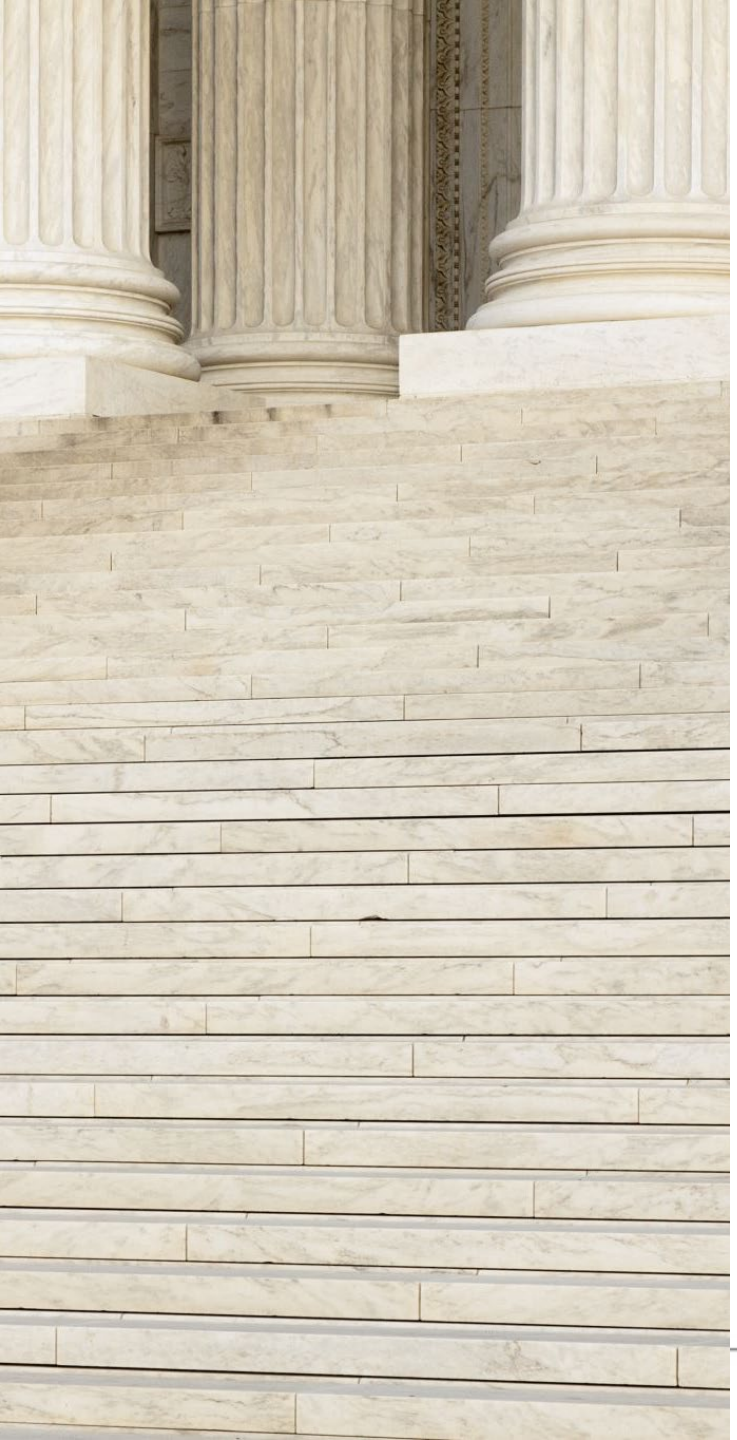
What do we do when we are faced with a moral dilemma or problem?

We draw on moral or ethics theories.



1 Principlism

- A more individualistic approach.
- Belmont Report (1979):
  - Respect for autonomy
  - Beneficence and non-maleficence.
  - Justice.



2 Utilitarianism

- A shift from a more autonomous, individualistic approach to a more communalistic, utilitarian approach.
- Focused on "*for the greater good*".
- Used in guiding the ethics of Public Health.
- During COVID Public Health Ethics had to be used.
- Certain individual rights were limited for the purpose of saving the most possible lives.
- Personal privileges ended where public peril began, e.g. lockdown, required self-isolation, quarantine measures, vaccination and compulsory wearing of masks.
- Also impacted on our research.

The Siracusa principles had to be acknowledged and followed:

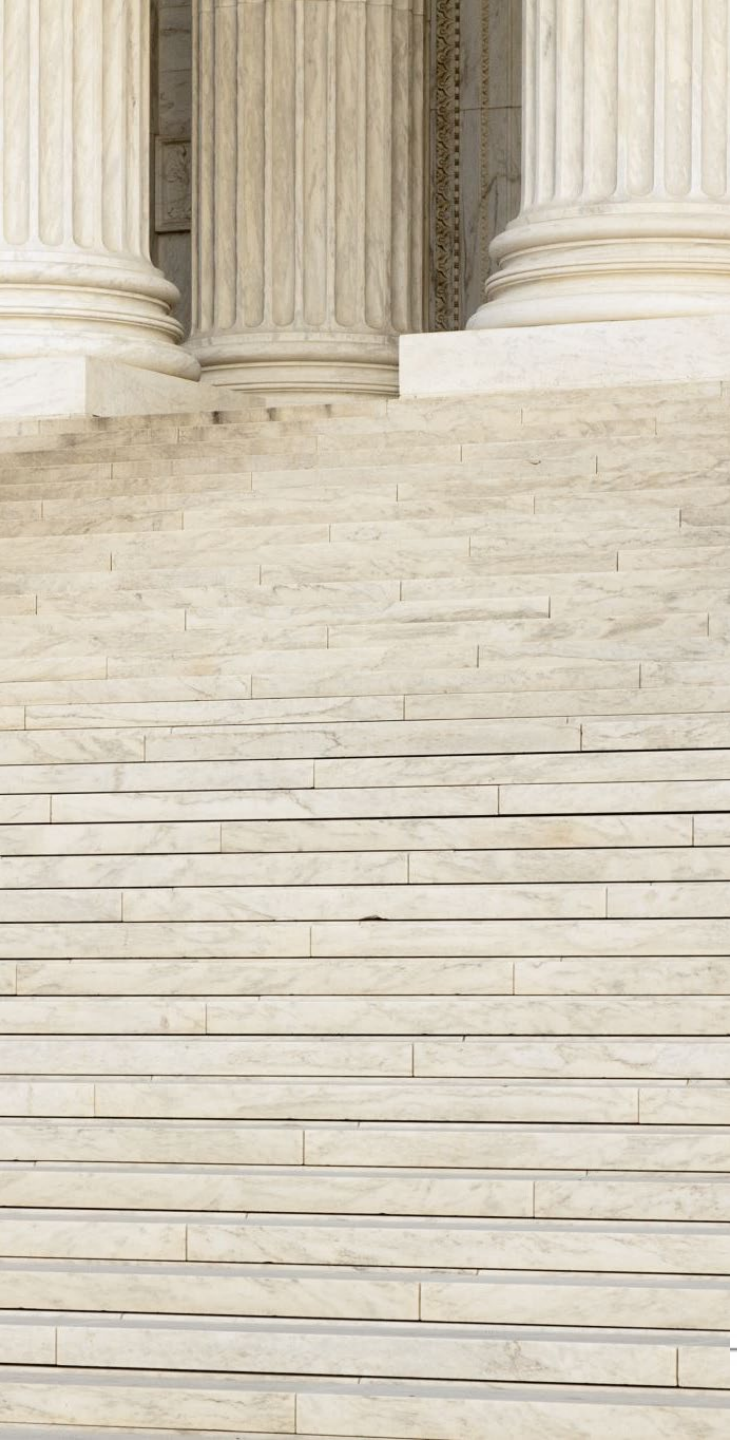
Any restrictions must be based on law.

Based on a legitimate objective.

Be strictly necessary to achieve the objectives.

Be the least restrictive and intrusive means necessary to achieve the same objectives.

Based in science and thus not arbitrary, unreasonable or discriminatory (United Nations Economic and Social Council, 1985).



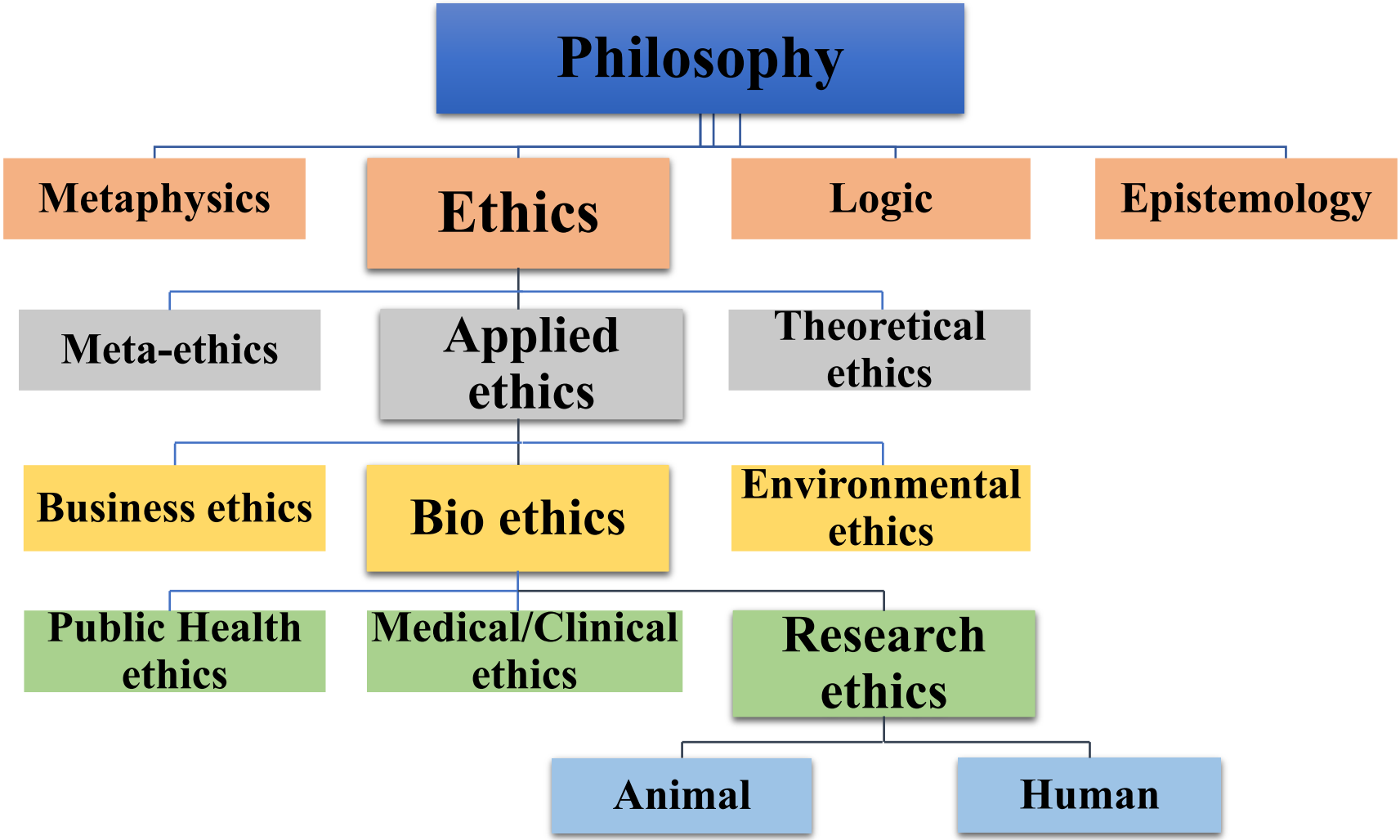
3 Kantian deontology

- Rule morality.
- Duty plays a pivotal role.

4 Virtue ethics

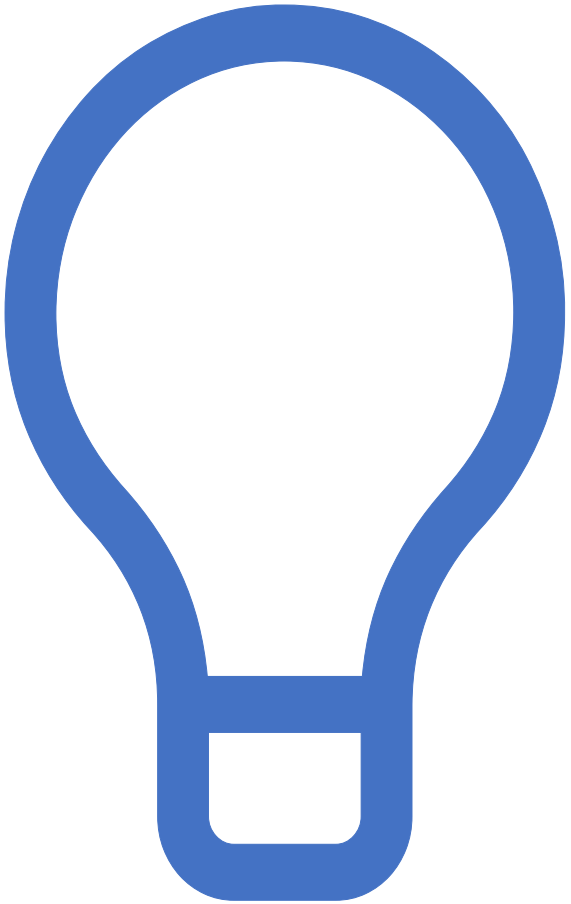
- Also referred to as character ethics.
- Focus is on character traits and less on the quality of the acts.

The Origin of Research Ethics



What then is Research Ethics?

- How do researchers know what the “right thing is to do”?
- How do research ethics committees (RECs) know what are the “right things to look for” or what advice to give to the researcher to do?



Research Ethics

- Important to adhere to ethical principles to protect the dignity, rights, and welfare of research participants (both humans and animal) (Resnik, 2015:2).
- Governments have an obligation to protect and promote the liberty and welfare interests of human research participants (Jacobsen, 2020:5) as well as animals.
- Governments and institutions do so by creating regulations, guidelines, and oversight structures like Research Ethics Committees (REC) (Elger, 2016:5).
- As such, all research should be reviewed by a REC to ensure that the appropriate ethical norms and standards are being upheld (Greenwood, 2016:514).
- For health or health-related research the review must be done by an approved National Health Research Ethics Council registered REC (NHA no 51 of 2003).
- **DEF: Research ethics is thus the set of rules that govern the norms and standards of conduct for researchers on how research is performed and how it is disseminated** (Wallace & Sheldon, 2015:272, Greenwood, 2016:514).

Regulatory frameworks

For humans:

Within the South African context, all health or health-related research ethics is regulated by:

- The National Health Act No 61 of 2003.
- The Regulations Relating to Research with Human Participants No 719 of 2014.
- The Department of Health's Ethics in Health Research: Principles, Processes and Structures (second edition) (DoH 2015).

Note: For researchers not doing health or health-related research these guidelines do provide at least some *minimum norms and standards*.

For animals:

- The DoH 2015.
- The SANS (revised version 2021).

Research ethics guided by:

3 Principles

8 Norms and standards

The 3 principles underlying health research ethics

NB *Ethical principles provide a basis on which specific rules may be formulated, criticised and interpreted.*

For South Africa the principles are:

- Beneficence and non-maleficence.
- Distributional justice (equality).
- Respect for persons (dignity and autonomy) (privacy and confidentiality) (DoH, 20215).

The 8 key norms and standards:

- Relevance and value.
- Scientific integrity.
- Role-player engagement.
- Favourable risk-benefit ratio.
- Fair selection of participants.
- Informed consent.
- Ongoing respect for enrolled participants.
- Research competence and expertise.

The 8 key norms and standards:

1. Relevance and value

- Research should at all times be relevant and responsive to the needs of the people of South Africa (DoH, 2015:16).
- The research proposal should explain:

➢ The anticipated contribution to knowledge generation.

➢ How the findings might translate into products, interventions, processes or services likely to improve standards and wellbeing of the research participants.

- Research should be scientifically or societally beneficial to be relevant.

2. Scientific integrity

- Scientific integrity is not the same as research integrity but only a part thereof.
- The study's design and methodology are vital for research integrity (DoH, 2015:17).
- A sound design and methodology will result in reliable and valid data and outcomes that address the research objectives.
- The study must be designed to be feasible, given the social, political, and cultural environment in which it is being conducted (Petersen, 2017:165).

The two principles important for *scientific integrity*:

1) Foster a culture of integrity in the scientific process.
2) Evidence-based policy interest must not interfere with scientific integrity.

The nine best practices of scientific integrity

1) Universal training in robust and up to date scientific methods.
2) Strengthen scientific integrity oversight and processes by focussing on both ethics and conduct.
3) Encourage reproducibility of research through transparency.
4) Strive to establish open science.
5) Develop and implement educational tools to teach communication skills that uphold scientific integrity.
6) Strive to further strengthen the peer review process.
7) Scientific journals should publish unanticipated findings that meet standards of quality and scientific integrity.
8) Seek harmonization and implementation among journals for transparent processes for correction and/or retraction of published papers.
9) Design rigorous and comprehensive evaluation criteria that reward the highest standards of research integrity (Kretser, Murphy, Bertuzzi et.al., 2019).

3. Role-player engagement

- Researchers should engage key role players at *various stages of planning and conducting* research to:

➢improve the quality and rigour of the research;

➢increase the acceptability to the key role players;

➢harness role player's expertise where possible; and

➢offset power differentials where these exist (DoH, 2015:16).

- Role-players can refer to stakeholders, academic or non-academic role-players, trans sectoral role-players, communities etc.

- Where research is conducted in the community involving stakeholders, the researcher should have *ongoing plans of consulting* with the community and stakeholders to prevent potential harm during and after research (DoH, 2015:17).

4. Favourable risk-benefit ratio

- A risk-benefit analysis should *precede* carrying out the research and favouring a ratio where the potential harm is outweighed by the benefits (DoH, 2015:16).
- Both *magnitude* or *seriousness* of harm and the *possibility of its occurrence* should be addressed (Kumar, 2017:126).
- If there are risks involved, there should be *justification* that demonstrates the anticipated importance and value (Koepsell, 2016:10), as well as how these will be *mitigated*.

5. Fair selection of participants

- Recruitment, selection, exclusion and inclusion (criteria) of participant must be *just* and *fair* and based on *scientific principles* (DoH, 2015:16).
- Persons should not be *excluded unreasonable* or unfairly.
- Persons should not be *unfairly targeted* for research.

6. Informed consent

- A *constitutional right* for all SA citizens.
- Research must be *voluntary* and predicated on *informed ch*oices.
- This must take place *before the research commence* and *affirmed during* the study (ongoing consent process) (Tauri, 2018:11).
- Should be *written*.

7. Ongoing Respect for enrolled participant

- Research participants have the right to both privacy and confidentiality (DoH, 2015:17).
- *Privacy* refers to while gathering the data.
- *Confidentiality* refers to how confidentiality of data is maintained.
- Data management plans and secure data management systems is essential.
- POPIA adherence essential.

8. Researcher competence and expertise

- Researchers must be suitably *qualified* and technically *competent* (DoH, 2015:17).
- The *principal investigator (PI)* or research supervisor has primary responsibility to ensure safety and wellbeing of participants (Osuji, 20108:105).

What then is Research Integrity?

Definition:

The active adherence to specific *principles* and *responsibilities* that becomes visible in

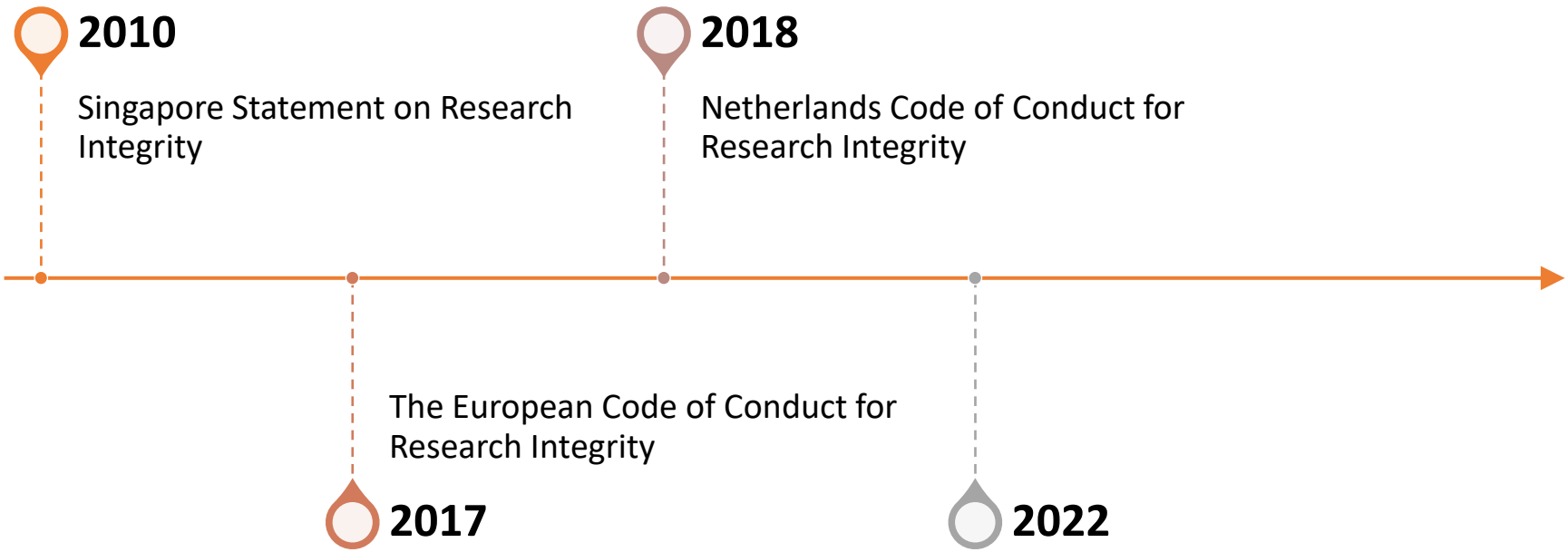
Responsible Conduct of Research

(RCR).

Research Integrity

- The *cornerstone* of scientific research.
- Adherence to *ethical principles and norms and standards* of ethical research.
- Commitment to *intellectual honesty* and *personal responsibility* for one's actions and to a range of practices characterising Responsible Conduct of Research (RCR) (See responsibilities).
- Adoption of these ethical principles, norms and standards and responsibilities of practice as a *code of conduct* and *personal credo* and not simply accepting it as impositions by rule-makers.

A few guiding codes for research integrity



Research Integrity guided by

4 Principles

14 Responsibilities

(Singapore Statement on Research Integrity, 2010)

The 4 Principles of RI

SINGAPORE STATEMENT (2010)	EUROPEAN CODE OF CONDUCT (2017)
▪ **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.	• **Honesty** to develop, undertake, review, report, communicate research in transparent, fair, full and unbiased way. • **Accountability** from idea to publication, for management and organisation, training, supervision, mentoring and wider impacts. • **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and environment. • **Reliability** to ensure quality of research, reflected in design, methodology, analyses and use of resources.

The 14 responsibilities of RI

Singapore Statement (2010)

1. **Integrity:** Trustworthiness of the research.
2. **Adherence to regulations:** Be aware and adhere to regulation etc.
3. **Research methods:** Employ appropriate research methods, base conclusions on critical analysis, report findings and interpretations fully and objectively.
4. **Research records:** Clear, accurate records to allow for verification and replication.
5. **Research findings:** Share openly and promptly.
6. **Authorship:** Take responsibility for contributions to all publications, funding, reports and representations. Authors should be *all those* and *only those* who meet the criteria of authorship.

Some issues concerning authorship

- Authorship is like a two sided coin:
  1) Credit
  2) Accountability
- Several best practice criteria or guidelines e.g. **COPE** (Guidelines on Publishing Ethics)

I would like to refer to the **International Committee of Medical Journal Editors** (ICMJE) (2018): *Criteria for authorship credit*.

Authorship credit should be based on the following **4 criteria**:

1. Substantial contributions to *conception and design* of the work, **OR** *acquisition* of data, *analysis* or *interpretation* of data for the work; **AND**
2. *Drafting* the work or *revising* it critically for important intellectual content, **AND**
3. *Final approval* of the version to be published; **AND**
4. Agreement *to be accountable* for all aspects of the work in ensuring that questions related to accuracy or integrity of any part of the work are appropriately investigated and resolved.

NB Authors should meet conditions **1, 2, 3** and **4.**

7. **Publication acknowledgement:** Acknowledge those who made significant contribution e.g. writers who do not meet inclusion criteria, funders, sponsors etc.
8. **Peer review:** Provide fair, prompt, rigorous evaluations, respect confidentiality.

Note: Reviewers should at all times display *moral integrity*, *transparency, responsibility* and profound *accuracy* when judging and reporting research work of their peers (Napolitani *et al.*, 2017).

Examples of peer review:

- Review of student's work
- Review of articles for journals
- Examination of a thesis or dissertation
- External moderation
- Panels for promotion
- Review for funding applications
- Review for scientific and/or ethics committees

9. **Conflict of interest:** Disclose all conflicts of interest that could compromise trustworthiness.
10. **Public communication:** Limit professional comments to recognized expertise and not personal views.
11. **Reporting irresponsible research practices:** Report to appropriate authorities any suspected breaches/transgressions (irresponsible/questionable research practices) or research misconduct (FFP) (NB As guilty if you don't report this).
12. **Responding to irresponsible research:** Institutions, journals, organisations committed to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices e.g. SOPs. Actions should be taken promptly.
13. **Research environment:** Research institutions should create and sustain environments that encourage integrity through education, clear policies, and responsible standards for advancement, while fostering environments that support research integrity.
14. **Societal considerations:** Researchers and research institutions should recognize that they have an ethical obligation to weigh societal benefits against risks inherent in their work.

What is Responsible Conduct of Research (RCR)?

The act of making Research Integrity (RI) visible

The practice of scientific investigation with responsibility and integrity through an awareness and application of established ethical principles, research norms/standards and in the responsible performance of all activities related to the research.

Some building blocks of RCR already mentioned under responsibilities:

Authorship

Peer review

Collaborative research

Plagiarism

Conflict of interest

Research involving humans and/or animals

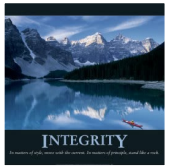
Data management

Research misconduct

Financial responsibility

Environmental/ social dimensions of research

Mentoring



Research, ethics and society

Research Ethics & Research Integrity Tree

HOW THEN DO WE MANAGE RESEARCH INTEGRITY?

THE INTEGRATED RESEARCH INTEGRITY MANAGEMENT SYSTEM (IRIMS) (Greeff, 2021)

Integrated Research Integrity Management System (IRIMS)

Foster a ***climate*** of Responsible Conduct of Research (RCR).

i. Support

ii. Organization

iii. Communication

iv. Training

Effectively manage ***potential breaches*** in research integrity through acts of:

i. Research non-compliance

ii. Violation of good research practice

iii. Research misconduct

1) How do we foster a climate of RCR?

Through an integrated research integrity management system (IRIMS) available to:

- Managers
- Researchers
- Postgraduate students

A summary of the framework of fostering a climate of RCR (Greeff, 2021)

Area	Topic	
Support	Research environment	
	Research study supervision	
	Mentoring	
Organization	Research ethics structure	
	Scientific committee structure	
	Integrated Research Integrity Management System	
	Data practices and management	
	Fair research assessment practices	
Communication	Research collaboration	
	Declaration of interests	
	Stakeholder/external organization communication	
	Publication and communication	
	Research ethics and research integrity webpage	
Training	Research ethics and research integrity training	
	Academics	*Postgraduate students*

2) Focus on managing breaches in RI

A system when we are faced with ***questionable research practices*** or even worse, **research misconduct**.

NWU:

* Research misconduct: Office of the Registrar (staff) or Student Judicial Office (postgraduate students)

* Research integrity officers (RIO) in the DD: R&I, FHS and the Office of the DVC: R&I (rest of the NWU)

But what happens to other **breaches/transgression of a lesser nature** (questionable research practices) than research misconduct?

Management of transgressions

Managed within the “NWU policy on academic integrity” (2018 revised 2021).

An initial intra-faculty process.

Focus on *restorative actions* and *mentorship* and less punitive or disciplinary in nature.

If, however, it is *research misconduct* it is escalated to the student judicial office or the office of the registrar.

CONTINUUM OF POTENTIAL BREACHES IN RESEARCH INTEGRITY (Greeff, 2021)

What are these acts that impact on the value or quality of research? (Greeff, 2021)

Research Non-Compliance

Any violation of:

- Any institutional and/or REC policies, procedures and regulation governing human or animal research.
- Any deviation from the REC-approved proposal/protocol.
- Types:

➢ Minor

➢ Serious

➢ Continuous

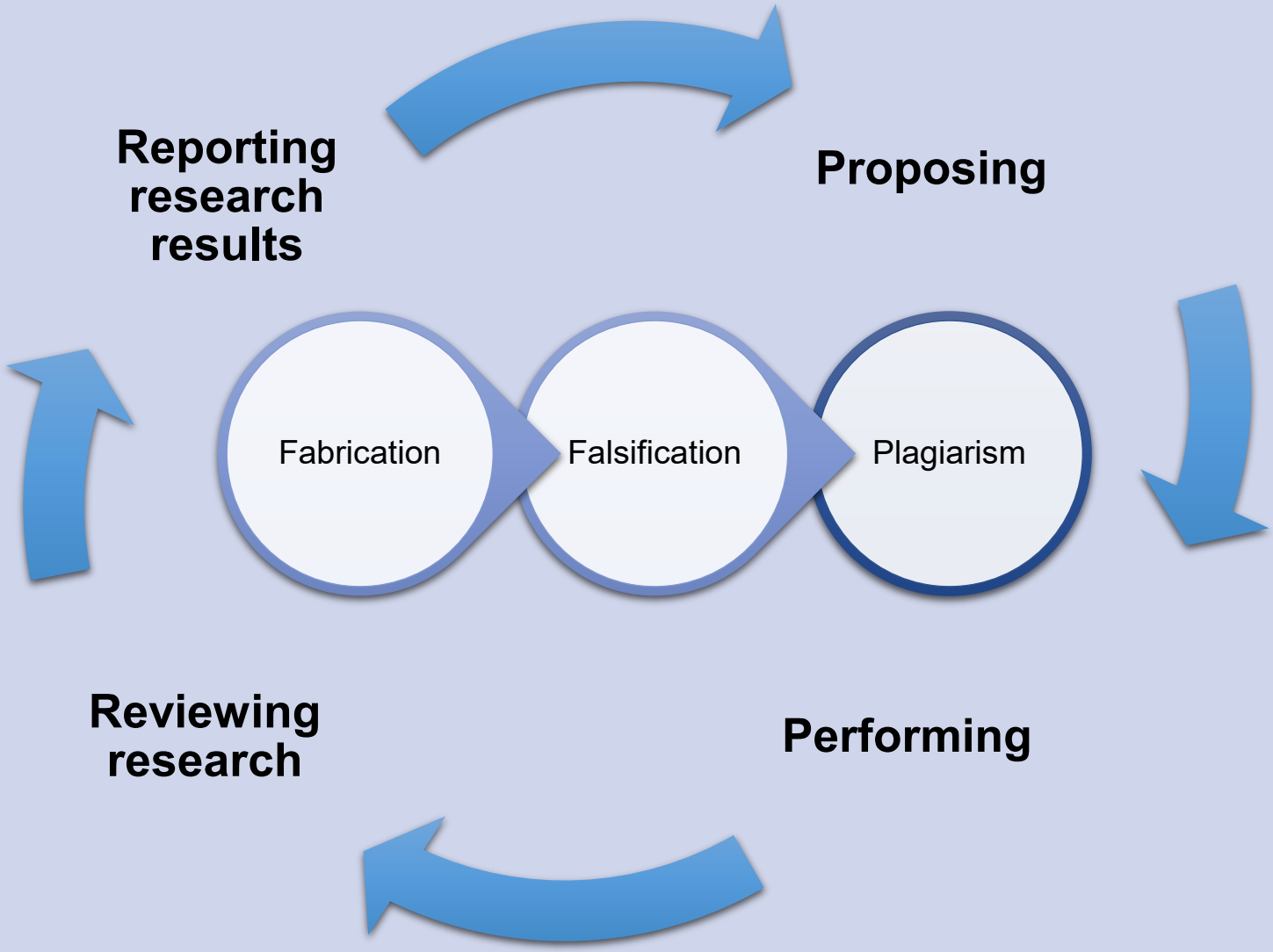
Violation of good research practice

Acts that damage the integrity of the research process or of researchers.

(Can also be continuous)

Research Misconduct

- Misconduct involves ***intentional deception.***
- Referred to as **FFP**.



Fabrication	Falsification	Plagiarism
Making up data or results and recording or reporting the fabricated material.	Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represent-ted in the research records.	The appropriation of another person's ideas, processes, results, or words without giving appropriate credit. (*Also see definition in the NWU Policy on Academic Integrity*).

Processes and procedures

- Overarching IRIMS guidelines.
- 7 Standard Operating Procedure (SOP) documents:

1) SOP_NWU Research Integrity_1. Management of Research Non-compliance and/or Violation of Good Research Practice.

2) SOP_NWU Research Integrity_2. Management of Continuous Research Non-compliance and/or Violation of Good Research Practice.

3) SOP_NWU Research Integrity_3. Management of Research Misconduct.

4) SOP_NWU Research Integrity_4. Management of the Research Integrity Appeals Process.

5) SOP_NWU Research Integrity_5. Management of Plagiarism and/or Copyright Infringement by External Authors.

6) SOP_NWU Research Integrity_6. Management of a Referral Received from the Registrar as a Breach in Research Integrity.

7) SOP_NWU Research Integirty_7. Management of Whistleblowing Pertaining to Research Ethics and Research Integrity.

Two important committee structures:

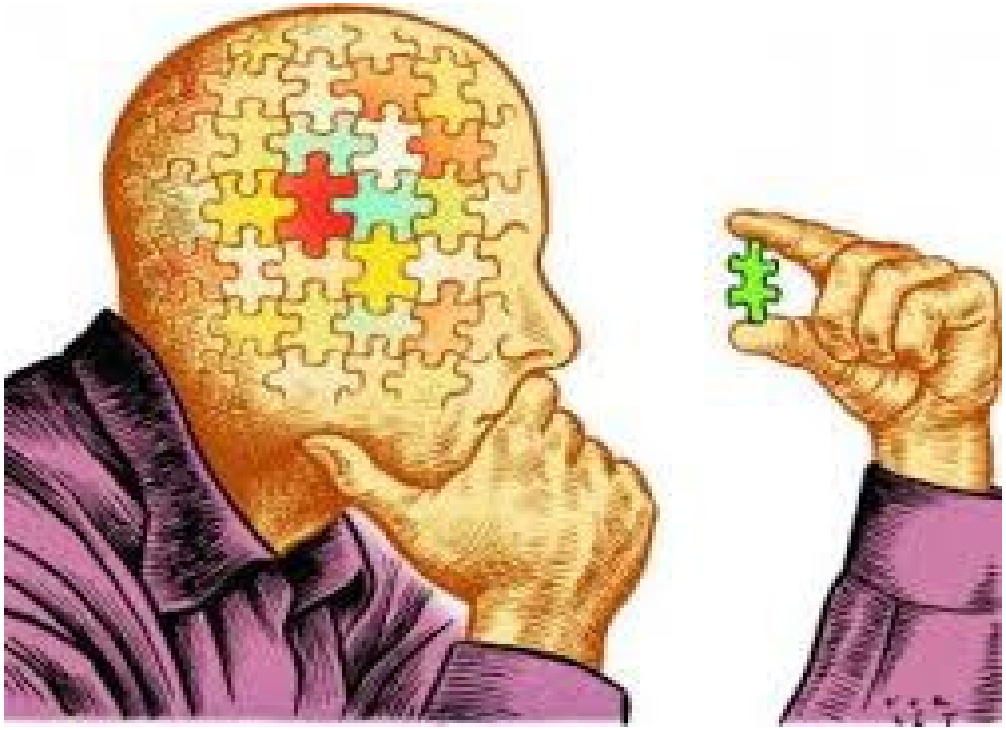
A Standing Research Integrity Committee (SRIC) appointed in the Faculty and consisting of the following members:	Empanelled Research Integrity Committee (ERIC) for only handling research noncompliance and violation of good research practice:
• Chairperson: DD: R&I. • Research Integrity Officer (RIO in the office of the DVC: R&I). • Chairperson or Head of the Ethics Office. • A Research Director in the Faculty knowledgeable in the management of RI (*appointed for three years*). • Secretariat.	• SRIC + • Research Director (RD) (where the researcher resides). • School Director (SD) (where the researcher resides). • An independent person (expert).

Breaches	Level of management	Structure
• Research non-compliance • Violation of good research practice	Intra-faculty (Restorative under mentorship) **SOP 1:** Management of Research Non-compliance and/or Violation of Good Research Practice	ERIC
Continuous: • Research non-compliance • Violation of good research practice	Intra-faculty (From the IRIMS to an intra-faculty disciplinary system involving HR) **SOP 2:** Management of Continuous Research Non-compliance and/or Violation of Good research practice	SRIC
Research misconduct (FFP)	Escalated to institutional level: • Office of the Registrar (Staff member) • Student Judicial Office (Postgraduate student) **SOP 3:** Management of Research Misconduct	SRIC
Other	**SOP 4:** Management of the Research Integrity Appeals Process **SOP 5:** Management of Plagiarism and/or Copyright Infringement be an External Author **SOP 6:** Management of a Referral from the Registrar as a Breach in Research Integrity **SOP 7:** Management of Whistleblowing pertaining to Research Ethics and Research Integrity	SRIC

An intertwined “whole” of Research Quality, Research Ethics, Scientific Integrity and Research Integrity to ensure RCR.

Moral balancing of the scale during RCR

Questions and answers

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