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Promoting responsible research conduct in an academic context: 'Compliance' versus 'responsibility'

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Outline:

1. Introduction
2. A ‘successful’ researcher and a ‘good’ researcher: Is there a difference?
3. Where are we?
4. Developing the next generation of ‘good’ and ‘successful’ researchers: 3 strategies
   - Training and Mentorship.
   - Institutional culture
   - Visible codes and policies

"***Research is based on the same ethical values that apply in everyday life, including honesty, fairness, objectivity, openness, trustworthiness, and respect for others***". (*On Being a Scientist. 3rd Ed. NAP. 2009)*

Reports of scientists 'being bad' seem to be making headlines rather a lot these days!

Henry K. Beecher.

First Prof of Anesthetics at Harvard
1966 NEJM article "Ethics and Clinical Research"
22 Examples cited of unethical published research.

"……the more reliable safeguard provided by the presence of an intelligent, informed, conscientious, compassionate, responsible investigator."

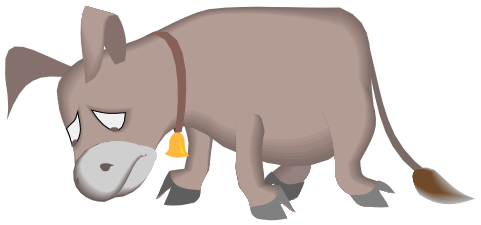
What is a **'successful researcher'**?
What is a **'good researcher'**?
Are the terms interchangeable?
Are all **'successful researchers'** also **'good researcher's**?
How do we ensure that the above is indeed the case?

Successful researcher checklist:

- ☑ Publication record
- ☑ Successful grant applications: NIH, USAID etc
- ☑ Total $ funding received
- ☑ International/NRF rating
- ☑ Peer recognition
- ☑ Awards from professional societies/ institutions
- ☑ Successful Masters and PhD students supervised **etc**

Challenges faced by the successful clinical researcher

- Balancing clinical practice, teaching with research- a tough ask!
- Intensely competitive research environment
- Limited pool of resources
- Navigating multiple sets of funder rules and regulations
- Navigating complex research ethics committee (REC/IRB) application procedures and approval requirements (often multiple times!)
- Navigating local and international rules and regulation for clinical research etc



‘SUCCESSFUL’ RESEARCHER

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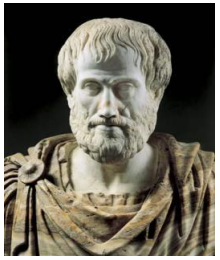
‘GOOD’ RESEARCHER

How do we get there?



Aristotle's approach to ethics

Aristotle would consider the question **" What is a 'good' researcher"?** by saying first we need to contemplate what it means to have a research career, **in the context of striving for a situation of optimal human flourishing for both the researcher himself and for the world in which he lives** (what the ancient Greeks called *eudaimonia*).

In order to achieve this Aristotle would argue that this researcher would have to acquire and develop, certain qualities or character traits, known as *aretē* in Greek.

Charater traits or Qualities (*Aretē)* of a 'good' researcher. i.e a deeply entrenched personal ethical value system.

- **Integrity**
- **Trustworthiness**
- A sense of **Justice**
- **Courage**
- **Discernment**
- **Respect or Respectfulness**

‘Ethic of Responsibility’

- 20th Century: Max Weber, Zygmunt Bauman

- Rules, codes and regulations can become structures to hide behind and almost promote a reduction in individual ethical responsibility for the value-choices we have to make and for being accountable for those choices.
- *E.g taking informed consent for a placebo controlled CT:*

TWO APPROACHES:

- Where we are (largely!)

Where we need to place more emphasis on, going forward!

COMPLIANCE FOCUSED

'ETHIC OF RESPONSIBILITY'

TWO APPROACHES:

- Acts and Regulations
- Rules to cover most eventualities and circumstances
- Training to teach systems of 'rules and 'codes' **GCP!**
- Bureaucratic systems to monitor compliance
- A 'one-size-fits-all approach' to review and approval of research (SA)

- Ethical principles
- Training in critical thinking skills and the principles of ethical research
- Systems that promote individual accountability and responsibility
- A risk-based approach to review and approval of research

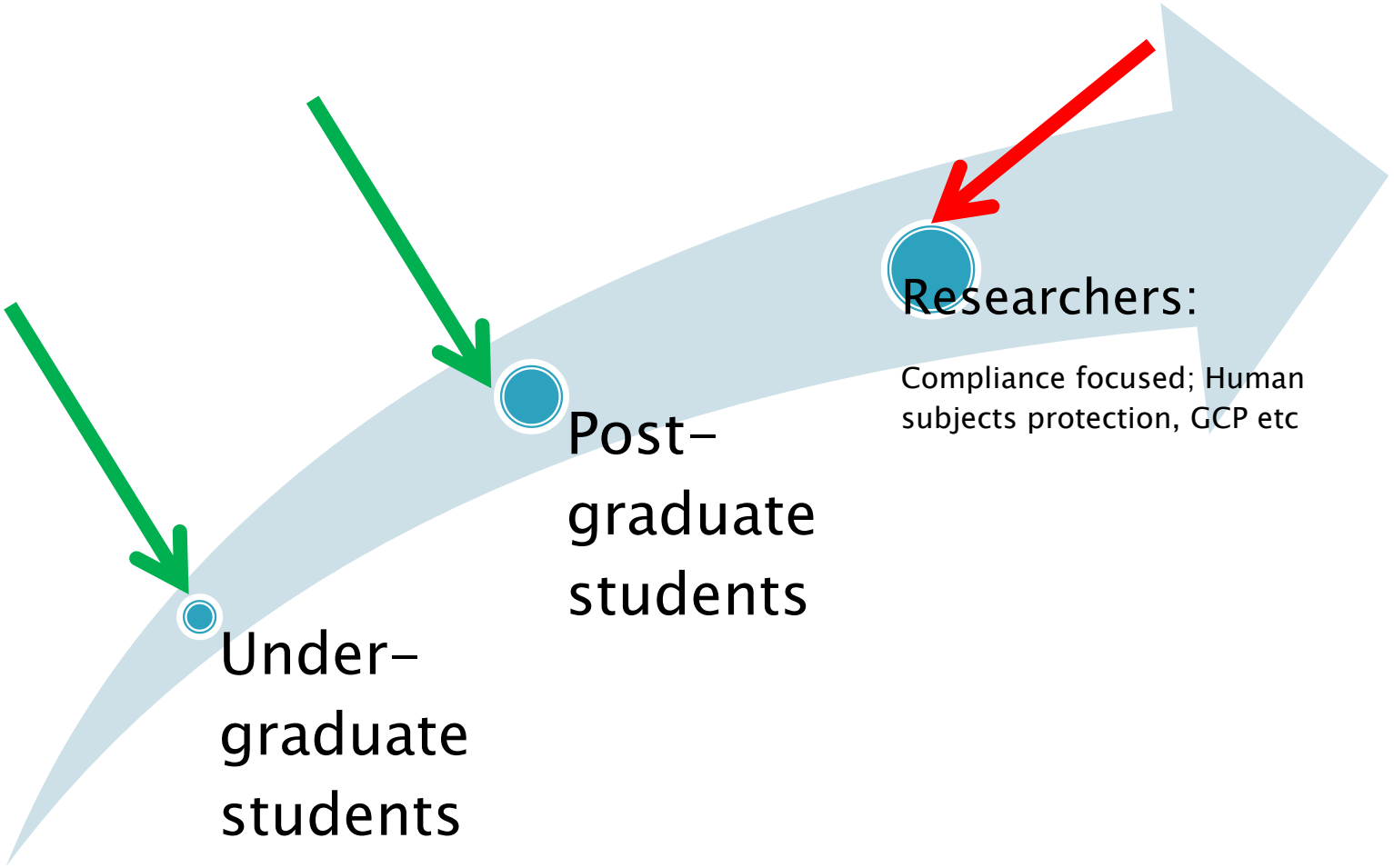
COMPLIANCE FOCUSED

'ETHICS OF RESPONSIBILITY'

Strategies for promoting the responsible conduct of research in an academic context:

- Training and Mentorship
- Institutional Culture
- Visible institutional codes and policies
- Early Warning systems (Anne Pope-UCT)

1(a) Training: Where to start?



Under-grad and post-grad student training in the responsible conduct of research:

- Start early and with a very small didactic component
- Teach an 'ethics of responsibility' with a broad focus
- More holistic approach; teaching critical thinking skills
- Emphasis on facilitated small group discussions of actual and constructed case studies.
- "Equip students well for the interlocking world in which they live" by cultivating their humanity (2003 Martha Nussbaum)
  - Socratic self examination-teaching students to be self critical and to think reflectively about their own values and the values of the society in which they live.
  - Narrative imagination- learn to identify with the life stories of others whose circumstances and contexts may be very different
- Creative curriculums that avoid just focusing on 'codes of conduct' and 'compliance'

1(b) Mentorship

- Mentors are often chosen because they are ‘Successful researchers’.
- Successful researchers may not always be well versed or sensitised to issues surrounding responsible research conduct and may have huge commitments of their own
- May well express irritation with bureaucracy often associated with ethics approval processes or other compliance issues etc to mentees
- Mentors also require training w.r.t promoting responsible research conduct prior to becoming mentors or supervisors
- Such training programs need to include discussions strategies for creating an institutional culture of research integrity and responsible conduct.

1(b) Mentorship

- David E. Wright Æ Sandra L. Titus Æ Jered B. Cornelison 'Mentoring and Research Misconduct: An Analysis of Research Mentoring in Closed ORI Cases' Sci Eng Ethics (2008) 14:323–336

This study investigated the mentoring of 45 ORI cases involving trainees, looking at 3 issues:

1. **Examining of raw data**– 73% of mentors had not looked at raw data
2. **Setting standards**: 62% of mentors had "little awareness" of the research they were supposedly supervising and had not set standards e.g keeping lab note books etc.
3. **Attention to stressful work environment**: 53% of trainee respondents attributed their stress levels as a contributing factor;62% said internal pressure to perform contributed; 38% attributed stress to time related issues.

2. Institutional Culture

How does an institution create a culture of responsible research conduct?

- Challenges:
  - Academic research environments are highly competitive
  - Time constraints and tight deadlines
  - Publish or perish!
  - Limited academic collegiality in some research groups or environments

2. Institutional Culture

- Strategies
  - Obtain leadership in responsible conduct of research (RCR) from the top- Training the trainers
  - Creating a culture of accountability from the bottom up (students)
  - Improving mentorship
  - Peer e.g. post-grade support groups
  - Minimizing bureaucracy, fast ethics turn-around times etc- (adequate administrative resources required)
  - Visible and clear policies
  - Creating opportunities for improving academic collegiality and communication.

Research Ethics Committees (IRBs)

- *Purpose: " to protect the dignity, rights and interests of human research participants"*
- **Not the enemy!** = institutional culture
- But will be if administrative support structure is poor, irrespective of review procedures
- There ARE ethical issues associated with clinical research, especially involving vulnerable populations which are not always immediately obvious or easily resolvable.
- REC review can be a learning process for all involved and can add value.
- Often very useful to invite researchers to REC meetings to discuss problematic aspects of a protocol

Research Ethics Committees (IRBs)

RECs face many challenges including :

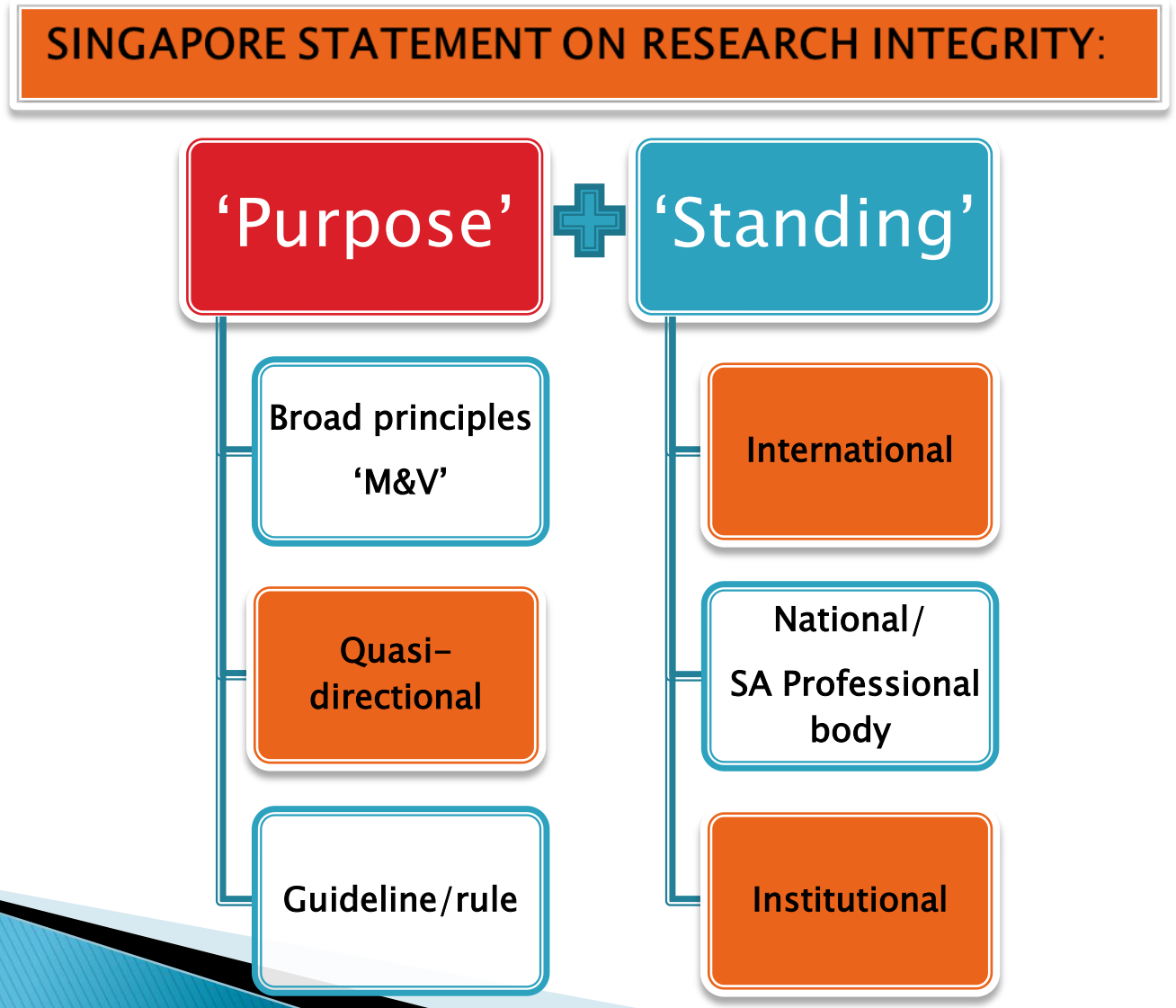
- complying with and ensuring compliance with externally imposed regulatory frameworks which do not always accommodate risk-based review
- Poor administrative and institutional support,
- Lack of recognition of the hours of voluntary additional work put in by academics who are researchers themselves
- Retention of experienced members and recruiting new members (the value of reciprocity often seem to be lacking in this context)

Investigators who have never sat on an IRB please take note!

3.Research Codes and Policies

- After providing training and mentorship and developing an institutional culture of research and academic integrity, institutions need to **adopt, endorse or develop clear research codes of conduct and policies**.
- Policies relating to the responsible conduct of research are not easily accessible on the websites of most SA Institutions, as compared with most top international institutions

Ethics codes for promoting responsible research conduct:



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.

PRINCIPLES

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

RESPONSIBILITIES

1. Integrity: Researchers should take responsibility for the trustworthiness of their research.

2. Adherence to Regulations: Researchers should be aware of and adhere to regulations and policies related to research.

3. Research Methods: Researchers should employ appropriate research methods, base conclusions on critical analysis of the evidence and report findings and interpretations fully and objectively.

4. Research Records: Researchers should keep clear, accurate records of all research in ways that will allow verification and replication of their work by others.

5. Research Findings: Researchers should share data and findings openly and promptly, as soon as they have had an opportunity to establish priority and ownership claims.

6. Authorship: Researchers should take responsibility for their contributions to all publications, funding applications, reports and other representations of their research. Lists of authors should include all those and only those who meet applicable authorship criteria.

7. Publication Acknowledgement: Researchers should acknowledge in publications the names and roles of those who made significant contributions to the research, including writers, funders, sponsors, and others, but do not meet authorship criteria.

8. Peer Review: Researchers should provide fair, prompt and rigorous evaluations and respect confidentiality when reviewing others' work.

9. Conflict of Interest: Researchers should disclose financial and other conflicts of interest that could compromise the trustworthiness of their work in research proposals, publications and public communications as well as in all review activities.

10. Public Communication: Researchers should limit professional comments to their recognized expertise when engaged in public discussions about the application and importance of research findings and clearly distinguish professional comments from opinions based on personal views.

11. Reporting Irresponsible Research Practices: Researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism, and other irresponsible research practices that undermine the trustworthiness of research, such as carelessness, improperly listing authors, failing to report conflicting data, or the use of misleading analytical methods.

12. Responding to Irresponsible Research Practices: Research institutions, as well as journals, professional organizations and agencies that have commitments to research, should have procedures for responding to allegations of misconduct and other irresponsible research practices and for protecting those who report such behavior in good faith. When misconduct or other irresponsible research practice is confirmed, appropriate actions should be taken promptly, including correcting the research record.

13. Research Environments: Research institutions should create and sustain environments that encourage integrity through education, clear policies, and reasonable standards for advancement, while fostering work 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.

The Singapore Statement on Research Integrity was developed as part of the 2nd World Conference on Research Integrity, 21-24 July 2010, in Singapore, as a global guide to the responsible conduct of research. It is not a regulatory document and does not represent the official policies of the countries and organizations that funded and/or participated in the Conference. For official policies, guidance, and regulations relating to research integrity, appropriate national bodies and organizations should be consulted. Available at: www.singaporestatement.org

‘INSTITUTION SPECIFIC’ CODES

- The development and implementation of codes of conduct for research, at an institutional level, is an essential component of an institutional strategy for promoting responsible research!

- These Codes/ Policies or Procedures must be
  - Visible
  - Easily accessible e.g in a web-based repository.

- **Research Integrity**
- **Research Ethics (Humans, Animals and the environment)**
- **Plagiarism**
- **Protection of whistle blowers etc**
- **Conflict of Interest** policy to cover research, procurement and nonfinancial conflicts of interests.
- **Allocation of authorship** and general principles of publication ethics.
- **Collaborative research**
- **Mentorship etc**
- **Record keeping and archiving of raw data**
- **Appropriate use of research funds.**

……Etcetera

Early warning systems (Anne Pope-UCT)

- Institutions needs to develop systems that can identify situations that could lead to things going wrong:
  - Pre-emptive action where there is a breakdown in collegial relations
  - Monitoring supervision of junior researchers
  - Responding to indications of 'high stress' levels among colleagues
  - Identifying and responding adequately to poorly functioning research support systems (including IRBs, clinical trial unit management etc)

Conclusion

- Institutions need to focus on 'in-house' strategies for **actively** promoting a culture of responsible research conduct in all spheres of research.
- It is not enough to just assume that the 'successful' researchers are by default also 'good' researchers.
- An 'ethic of responsibility' needs to go hand-in-hand with a commitment to compliance


THANK YOU FOR
LISTENING!