RESEARCH INTEGRITY AND RESPONSIBLE CONDUCT OF RESEARCH

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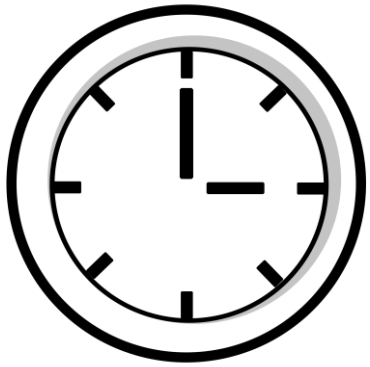
Program for the two and a half hour workshop

Time	Activity	Presenter
5 mins	Opening	Prof J du Plessis
2 hours 30 min	Presentation and interaction on research integrity and responsible conduct of research	Prof M Greeff and attendees



1. Introduction

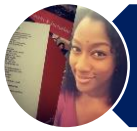
- The *value* and *benefits* of research are vitally dependent on the integrity of research (Singapore Statement, 2010).
- No matter where research is undertaken, there are *principles* and *professional responsibilities* that are fundamental to the integrity of the research (Singapore Statement, 2010).
- A scientist needs to develop a *strong sense of ethical responsibility* to apply at every stage of scientific inquiry (Abad-Gracia, 2019).
- Research *ethics is a subset* of research integrity.

- Some institutions have research integrity offices with research integrity officers (RIOs) responsible for upholding the research integrity at an institution.
- In the Faculty of Health Sciences at the NWU:
  - Integrated research integrity into the Ethics Office.
  - No to little involvement of the two RECs in this process.
  - Violation of good research practice and noncompliance handled in the Ethics office with a *restorative action in mind*.
  - If any possible misconduct involved referred to the Deputy Vice Chancellor Research and Innovation.
- Our own code of conduct at the NWU is formulated according to the Singapore Statement on Research Integrity (2010).

2. Definition of research integrity

Research integrity the *cornerstone* of scientific research.

Active adherence to *ethical principles* and *professional standards* essential for *responsible practice of research*.



Active adherence means adoption of principles and practices as *personal credo*, not simply accepting as impositions by rule-makers.

Adherence to a *code* or usually high *standard* of conduct.

Above all commitment to *intellectual honesty* and *personal responsibility* for ones actions and to *range of practices* characterising *responsible conduct of research*.

For the individual, research integrity is an aspect of *moral character* and *experience*.

Honesty is central to the relationship between researcher, participant and other interested parties.

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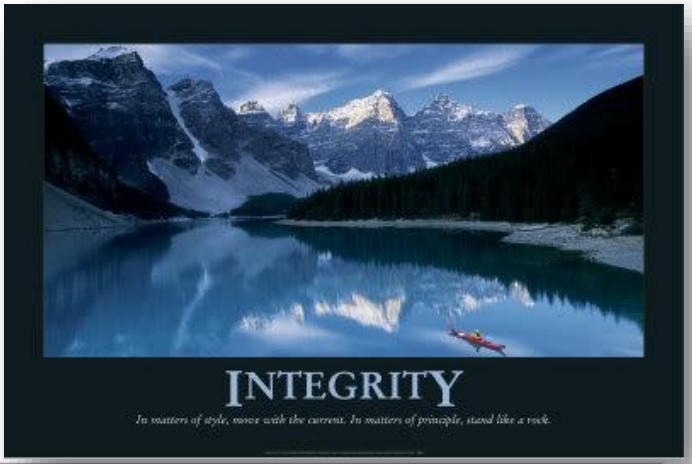
3. Why is research integrity important?

- Research integrity is the *commitment* - sometimes in face of adversity - to *trustworthiness of the research process* by the scientific community.
- It is important - even - critical because 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, and
  - Acknowledges and respect the intellectual contributions of other in the greater community (webGURU).



4. What is responsible conduct of research (RCR)?

- The *practice* of scientific investigation with integrity.
- Awareness and application of established *professional norms and ethical principles* in performance of all activities related to scientific research.
- Covers core *norms, principles, regulations and rules* governing practice of research.
- Critical for *excellence* and *public trust*.
- Includes most of *professional activities* that are part and parcel of a research career.

Themes usually covered in responsible conduct of research training:

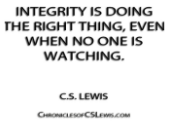
Authorship

Peer review

Collaborative research

Plagiarism

Conflict of interest



Research involving humans and/or animals

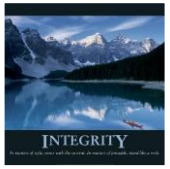
Data management

Research misconduct

Financial responsibility

Environmental/so-cial dimensions of research

Mentoring



Research, ethics and society

5. Two important international guiding documents

2010

Singapore Statement on Research Integrity

Developed 2nd World Conference on Research Integrity as global guide to Responsible Conduct of Research (RCR).

2017

European Code of Conduct for Research Integrity

This code applies to research in all scientific and scholarly fields.

- A basic *responsibility* of the research community is to:

- This code serves as a *frame for self-regulation* for each researcher.

- **It describes:**
  - Professional;
  - Legal;
  - Ethical responsibilities.
- **Acknowledges** the importance of institutional settings in which research is organised.
- **The interpretation of values and principles that regulate research may be affected by:**
  - Social developments;
  - Political developments;
  - Technological developments;
  - Changes in the research environment.

Note: For structure and meaningful flow, I will be combining these two documents in the presentation that follows.

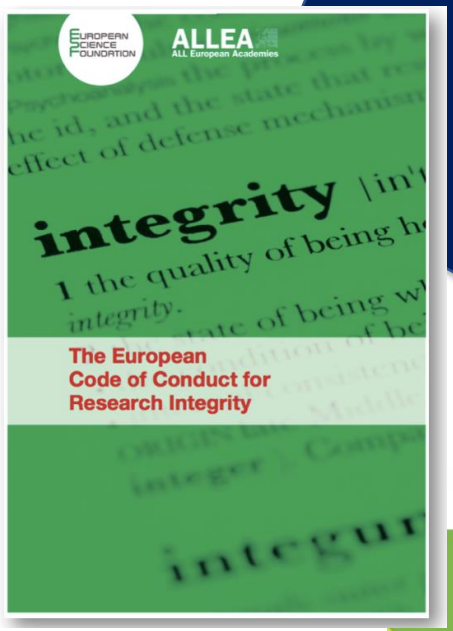
5.1 Principles

Some overlap but the European code more explanatory

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.

5.2 Responsibilities (SS) and good research practices (ECC)

The way in which the two documents are presented focus on slightly different aspects or overlap but are all essential for upholding research integrity.



5.2.1 Fourteen responsibilities

Singapore Statement

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.

Due to many concerning practices I would like to refer to the criteria of authorship according to **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.**

- Acquisition of funding, data collection, general supervision of research group, alone, does not justify authorship.
- All persons designated as authors should *qualify for authorship*, and all those who qualify *should be listed*.
- Much attention given to **disclose conflict of interest**: when professional judgement concerning *primary interest* (such as patient welfare or validity of research) may be influenced be a *secondary interest* (such as financial gain). Never secondary over primary.

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).

Includes aspects like:

- 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 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 research misconduct (FFP, other irresponsible research practices).
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. 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.

5.2.2 Eight good research practices

European Code of Conduct for Research Integrity(2017)

Practice	Description
1. Research environment	• Culture of research integrity. • Clear policies, procedures on good research practice. • Infrastructure for management/protection of data and research materials in all forms necessary for reproducibility, traceability and accountability. • Incorporate into hiring/promotion of researcher.
2. Training, supervision and mentoring	• Rigorous training in research design, methodology, analysis. • Develop appropriate, adequate training in research ethics and integrity, all made aware of codes and regulations. • All researchers (junior/senior) undertake training in ethics and integrity. • Seniors and leaders mentor teams to ensure proper research activity and culture of research integrity.

5.2.2 Eight good research practices (cont.)

Practice	Description
3. Research procedures	• Consider state-of-the-art in developing research ideas. • Design, execute, document research in careful, well-considered manner. • Use research funds conscientiously and properly. • Publish results in an open, honest, transparent, accurate manner; respect confidentiality. • Report results compatible with standards that can be verified and reproduced.
4. Safeguards	• Comply with codes, regulations relevant to their discipline. • Handle participants (human/animals/ biological/environment etc.) with respect and care according to ethical-legal provisions. • Due regard for health, safety, welfare of community, collaborators, others connected to the research. • Proposals consider/sensitive to diversity in age, gender, culture, religion, ethnic origin, social class. • Manage potential harms and risks relating to the research.

5.2.2 Eight good research practices (cont.)

Practice	Description
5. Data practices and management	• Appropriate stewardship/curation of data, research materials for reasonable period. • Ensure data access as open as possible, closed as necessary and using the FAIR principles (Findable, Accessible, Interoperable, Re-usable). • Researchers/institutions transparent about how to access or make use of data/research materials. • Acknowledge data as legitimate, citable product of research. • Contracts/agreements clear on intellectual property rights.

5.2.2 Eight good research practices (cont.)

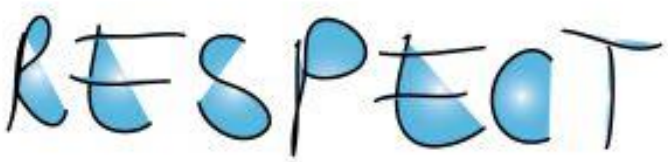
Practice	Description
6. Collaborative working	• All partners take responsibility for research integrity. • All partners at onset clear about goals/processes to communicate research as transparent/open as possible. • All agree at onset on expectations/standards concerning research integrity, regulations, intellectual property, how to handle conflict/cases of misconduct. • All properly informed and consulted about submissions for publications. • Factors usually affecting collaborations: Personal, disciplinary, institutional, resource availability (Murithi *et al.*, 2018).

5.2.2 Eight good research practices (cont.)

Practice	Description
7. Publication and dissemination	• All fully responsible for content unless otherwise specified. • All agree on sequence of authorship, acknowledging that authorship is based on significant contributions. • Authors ensure work available to colleagues: timely, open, transparent, accurate manner and honest to general public and social media. • Acknowledge important contributions by others. • All authors disclose conflict of interest. • Retract, publish corrections clearly. • Negative results as important as positive results for publication. • Researchers adhere to quality criteria no matter where they publish.

5.2.2 Eight good research practices (cont.)

Practice	Description
8. Review, evaluate and edit	• Researchers seriously take part in refereeing, reviewing and evaluation. • When reviewing for funding, publication, and promotion etc. done in a transparent and justifiable manner. • Withdraw from review if conflict of interest. • Maintain confidentiality. • Respect rights and seek permission to use ideas, data or interpretations.



5.3 Violation of research integrity

The European Code of Conduct for Research Integrity (2017)

The European Code of Conduct (2017) adds a third section should you violate research integrity

Before I refer specifically to what they state I would like to discuss a few concepts used in our documentation of the Faculty of Health Sciences, North-West University.

Honest human error	Non-compliance
Error – unintentional, negligence but not misconduct.	• Any violation of any regulation governing human or animal research or any deviation from the REC-approved proposal/protocol. • Non-compliance varies in nature, severity, frequency (*adapted from* UCT, 2013). It could be minor, serious or continuous.

Minor non-compliance

- A non-compliant incident that does not affect human participants' or animals' safety, compromise data integrity, violate participants' rights or welfare or affect participants' willingness to participate in research.
- Examples include but are not limited to:

❑ Missed deadline for a continuing review e.g. monitoring reports.
❑ Inadvertent errors due to inattention to detail.
❑ Misunderstanding or oversight (UCT, 2013).

Serious non-compliance

- An activity jeopardises human participants'/animals' safety, rights or welfare, or integrity of the data during research.
- Examples include but are not limited to:

❑ Conducting research with humans/animals without REC approval.
❑ Current REC-approved ICF do not describe all potential risks, alternatives.
❑ Failure to obtain voluntary informed consent.
❑ Deviation/failure adherence to approved proposal without prior approval.
❑ Failure to follow accepted procedures to exercise due care to avoid harm/discomfort to participants or research staff.
❑ Not showing integrity (ECCRI, 2017; UCT, 2013 and 2014).
❑ Enrolling human participants do not meet inclusion criteria or including those that adhere to exclusion criteria.

Serious non-compliance (continues)

- Not using approved REC documentation.
- Activities that compromise participant's privacy and confidentiality.
- Implementing substantive modifications to REC-approved proposals/protocols without prior REC approval.
- Continuing with research when REC approval has lapsed.
- Inadequate training and supervision of research staff.
- Copyright infringement.
- Negligent management of data security (adapted from the European Code of Conduct for Research.

Continuous non-compliance

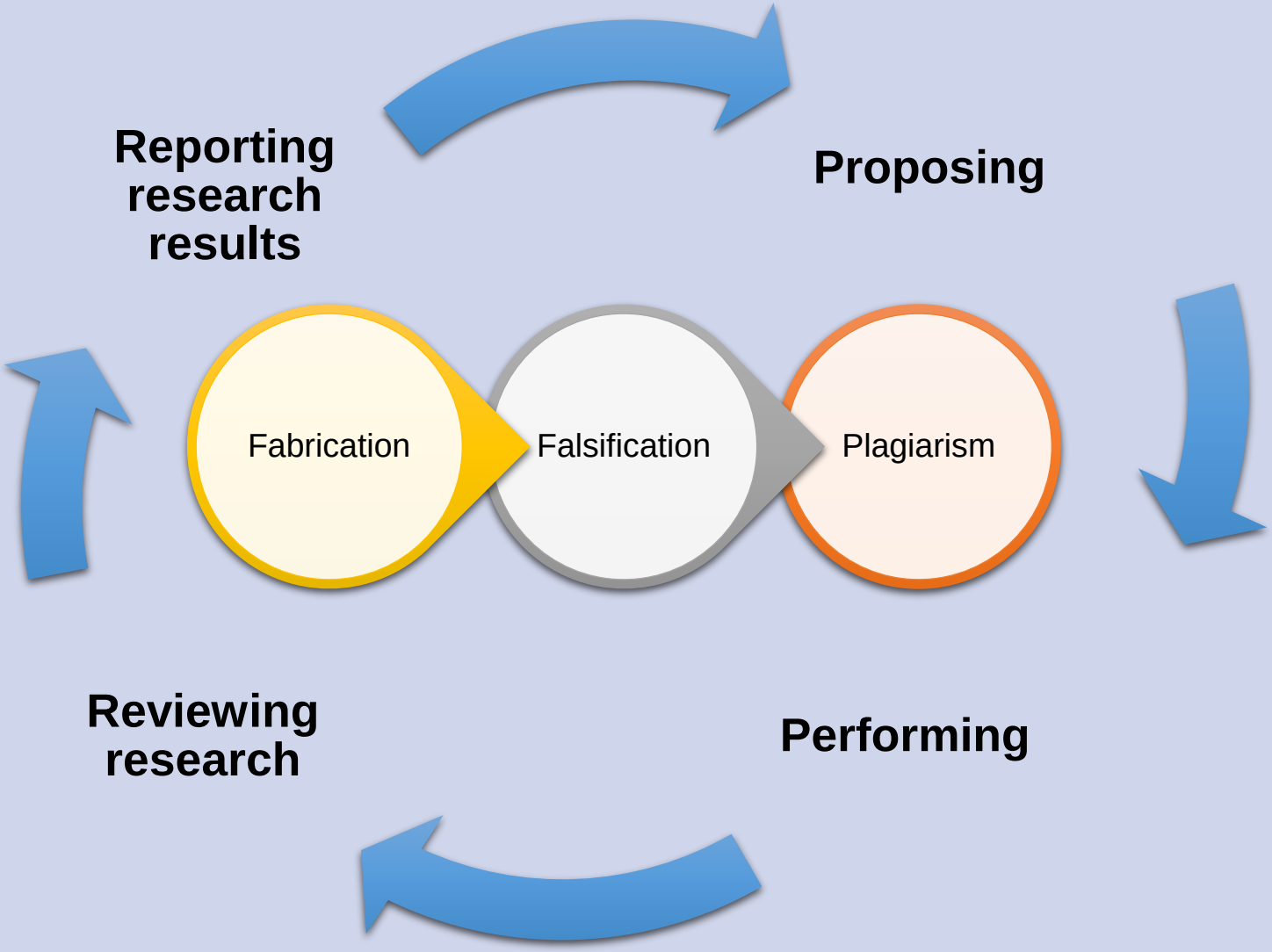
- A series of more than one non-compliant or violating behaviour in reasonable close proximity that, if unaddressed, may compromise the research integrity.
- This can be due to lack of knowledge or commitment on the part of the researcher(s).
- The conduct continues after the researcher has been explicitly made aware of the first instance of non-compliant or violating behaviour and that despite an attempt to assist the researcher in this regard, the conduct continues.
- Examples include, not limited to:

❑ Repeated failure to follow institutional and REC policies and procedures particularly after the researcher has been informed of the problem(s) and that corrective action needs to be taken.

❑ A researcher has a record of non-compliance, violations or misconduct over a long period or in a number of existing or previously approved studies (*adapted from* UCT, 2013).

Misconduct

- Misconduct involves intentional deception
- Research misconduct is defined 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.

5.3.1 Violation of good research practices

European Code of Conduct for Research Integrity (2017)

- Failing to follow good research practices:
  - Violates professional responsibilities.
  - It damages the research process.
  - Degrades relationships amongst researchers.
  - Undermines trust and the credibility of the research.
  - Wastes resources.
  - May expose research participants, users, society or the environment to unnecessary harm.


Violation of good research practices (ECC, 2017)
What these practices are:
Misconduct
Other unacceptable research practices
How to deal with them

5.3.1 Research misconduct and other unacceptable practices

European Code of Conduct for Research Integrity (2017)

Misconduct	Other unacceptable research practices
• Traditionally defined as fabrication, falsification, or plagiarism in proposing, performing or reviewing research or reporting research. • Seen as serious. • **Fabrication:** Making up results, recording as if they were real. • **Falsification:** Manipulating research materials, equipment, processes or changing, omitting or suppressing data or results without justification • **Plagiarism:** Using other people's work, ideas without giving proper credit to original source, violating rights of original author(s) to their intellectual outputs.	• In their most serious form they are sanctionable. • At the very least efforts to: ❑ prevent ❑ discourage ❑ stop them should be made through ❑ training ❑ supervision and mentoring ❑ the development of a supportive research environment

5.3.1 Research misconduct and other unacceptable practices (continues)

Other unacceptable research practices

- Manipulate/denigrate role of researchers in publications.
- Re-publish substantive parts of own earlier publications without duly acknowledge/cite original (self-plagiarism).
- Cite selective to enhance own findings.
- Withhold research results.
- Allow funders/sponsors to jeopardise independence.
- Expand bibliography unnecessary.
- Maliciously accuse researcher of misconduct/violations.
- Misrepresent research achievements.
- Exaggerate importance/practical applicability of findings.
- Delay/inappropriate hamper work of researchers.
- Misuse seniority to encourage violations of research integrity.
- Ignore putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations.
- Support predatory journals.

5.3.2 Dealing with violations and allegations of misconduct

- Must be handled in a consistent and transparent fashion
- The following principles are used during an investigation:

Integrity	Fairness
• Fair, comprehensive, conducted expediently without compromising accuracy, objectivity or thoroughness. • Conflict of interest declared. • Must be taken through to conclusion. • Confidentiality is maintained. • Protect “whistle-blowers”. • Procedures for dealing with this is publicly available.	• Due process is followed for all parties. • Persons accused are given full details of the allegations and allowed fair process for responding. • Actions taken proportionate to the severity of the violation. • Appropriate restorative actions are taken. • Anyone accused is innocent until proven otherwise.

5.4 Responsible research practice

Article by Swaen *et al*. (2018) about guidelines for responsible research practice in Epidemiology

- Evidence of irresponsibility in research practice that:
  - Scientific research practices are not sound.
  - That study results are not as reproducible as it should be.
- Detrimental research practices:
  - Methodological in nature
  - Selective reporting
  - Not reporting results
  - Protocol deviations
  - Data dredging (scooping out)
  - Misconduct

Three clear phases in responsible research practice

Phase 1: Preparation of the study	Phase 2: Conducting the study	Phase 3: Dissemination and aftercare
• Setting up the team • Constructing a meaningful question • Designing the proposal • Obtaining funding • Ethical review	• Human volunteers' protection • Data collection • Data analysis • Preparing reports	• Manuscript submission and reporting • Data archiving and sharing • Document archiving • Accountability and transparency (Swaen *et al*., 2018)

Note:

I would like to refer you to an excellent movie on research integrity that I include in the Basic of Research Ethics training course:

“On being a Scientist” (available on YouTube)

I thank you for listening