Cape Peninsula
University of Technology

creating futures

Being a Responsible Researcher and Research Ethics

Penelope Engel-Hills

Academic Year 2023

Being a Responsible Researcher

Being a Responsible Researcher

Historic Perspective
Introduction to Moral Philosophy
Research Integrity and Ethics
Ethical Principles
Ethics and Law
Risk/benefit analysis
Ethical Decision Making
The informed consent process
Research Misconduct
Conflict of Interest
Code of conduct

Historic Perspective

Research Ethics Timeline

Inspired by David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1620

- Francis Bacon in, *The Novum Organon*, argues that scientific research should benefit humanity.

1752

- Peer review procedures instituted for articles submitted to the *Philosophical Transactions of the Royal Society of London (*the world's first scientific journal, first published in 1665).

1830

- Charles Babbage published *Reflections on the Decline of Science in England, And Some of Its Causes.* He argued that many of his colleagues were engaging in dishonest research practices.

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1897

- Giuseppe Sanarelli injected yellow fever bacteria into five patients without their consent. All the patients developed the disease and three died.

1900

- Walter Reed exposed 33 participants to yellow fever. Six participants died, including two researcher-volunteers. Participants all signed consent forms.

1909

- Robert Millikan conducted research for which he later received a Nobel Prize for Physics. Later reported that he did not name his student as an author, even though Fletcher made key contributions e.g. the use of oil instead of water droplets for measuring electron energy.

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1932-1972

- The Tuskegee Syphilis Study, began in 1932 to investigate the effects of untreated syphilis in 400 African American men. Researchers withheld treatment even when penicillin became widely available in 1950s. The study forced to end in 1972.

1932-1945

- Japanese scientists performed morally abominable experiments on thousands of Chinese prisoners or war. The U.S. government agreed to not prosecute the scientists for war crimes in exchange for data from the biological and chemical weapons research.

1939-1945

- German scientists conducted morally abominable research on concentration camp prisoners. German scientists were prosecuted for war crimes in the Nuremberg Trials.

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1944-1980s

- The U.S. Department of Energy sponsored secret research on the effects of radiation on human beings (cancer patients, pregnant women, and military personnel).

1945

- V Bush wrote report *Science: The Endless Frontier* for President Roosevelt. The report defended the ideal of a self-governing scientific community free from significant public oversight.

1947

- **The Nuremberg Code, the first international code of ethics for research on human subjects, is adopted.**

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1956-1980

- Researchers conduct hepatitis experiments on mentally disabled children at The Willowbrook State School. They intentionally infected subjects with the disease and observed its natural progression. The experiments were approved by the New York Department of Health.

1957-1962

- In 1957, thalidomide is marketed as medication to treat morning sickness during pregnancy. About 10,000 infants, mostly in West Germany, are born with severe birth defects and 2,000 children die from thalidomide exposure. In 1960, Frances Kelsey, a drug reviewer for the FDA, refused to approve the drug.

1961-1962

- Stanley Milgram conducted "electric shock" experiments, to prove that people are willing to do things that they consider to be morally wrong when following the orders of an authority. Included a learner connected to electrodes. If the learner gave an incorrect response to a question, the researcher would instruct the teacher to push a button on a machine to shock learner. Teachers were willing to do this. (In reality, no shocks were given).

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1964

- **The World Medical Association published Declaration at Helsinki, Ethical Principles for Research Involving Human Subjects. The Helsinki Declaration has been revised numerous times, most recently in 2013.**

1973

- After conducting hearings on unethical research, including the Tuskegee study, the National Research Act in 1973, was passed. The Act authorizes federal agencies (e.g. the NIH and FDA) **to develop human research regulations requiring** institutions to **form IRBs to review and oversee research with human subjects**.

1979

- The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research publishes ***The Belmont Report: Principles of Ethical Research on Human Subjects*****.**

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1989

- The NIH requires that all graduate students on training grants receive education in responsible conduct of research.

1990

- In *Moore v. Regents of the University of California*, the California Supreme Court rules that researchers have IP rights in a cell line derived from Moore's tissue, and that Moore did not have any property rights in his own tissue. The Court also rules that the researchers violated Moore's right to informed consent. Most courts have followed this ruling, holding that patients no longer have rights to tissues leftover from surgeries or procedures or donated to researchers.

1999-2009

- Human research lawsuits increase dramatically with lawsuits against researchers, universities, pharmaceutical companies, and Institutional Review Board/REC members.

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

1999

- The U.S. require all people conducting or overseeing research on human subjects to have training in research ethics.

2010

- Jeffrey Beale published a list of what he calls “predatory journals” - profit-driven journals that charge high fees for open access publication, promise rapid publication, and have poor (or nonexistent) standards for peer review. Beale later withdrew his list due to pressure from journals.

2010

- The World Conference on Research Integrity releases the **Singapore Statement** on Research Integrity, a code of ethics for scientists in various disciplines.

Research Ethics Timeline Continued

David B. Resnik, Bioethicist

Cape Peninsula University of Technology

creating futures

2010

- Journalist Rebecca Skloot publishes a widely-acclaimed book about Henrietta Lacks, an African American woman who had cervical cancer and provided the tissue for a cell line known as HeLa (1951 at Johns Hopkins Hospital). Researchers were able to culture the cells and keep them alive, the first time that this was possible. Skloot interviewed Lacks' family and learned there was consent given and no compensation, which was a common practice at that time. Skloot decided to share profits from her book with the family. In 2013, the NIH reached an agreement with Lacks' family concerning access to genomic data from the cell line. A law suit is ongoing.

2022

- During the COVID-19 pandemic, scientists worked feverishly to conduct research that could help combat this public health crisis. To make data and results available as quickly as possible, many journals expedited their peer review process and scientists published articles on pre-print servers before undergoing peer review. The rush to publish led to the dissemination of some invalid, irreproducible, and falsified results. Dozens of COVID-19 papers had to be retracted or withdrawn. Two prominent biomedical journals, the New England Journal of Medicine and the Lancet, retracted papers after the editors learned that the healthcare analytics company Surgisphere, was not making the raw data available to independent scientists who found inconsistencies in the data and wanted to do an audit.

- **A work in progress**

Moral Philosophy

A Branch of Philosophy that explores morality and how we should live our lives contemplating what is right and wrong

In Research it guides us in what is right and wrong

Being Moral

Cape Peninsula University of Technology

creating futures

3 Branches:

1. Meta-ethics

Morality, Justice, Truth, Beliefs

2. Normative ethics

A framework for deciding right from wrong – what we ought to do.

3. Applied ethics

Addresses specific practical issues faced in daily life (e.g. lie to help a friend or colleague, application to your study)

Minimum Conception of Morality

Rachels J (2003) *The Elements of Moral Philosophy, McGraw Hill*

Cape Peninsula University of Technology

creating futures

Morality is, at the very least, the effort to guide one's conduct by reason – that is, to do what there are the best reasons for doing – while giving equal weight to the interests of each individual who will be affected by what one does.

Cape Peninsula
University of Technology
creating futures

A Moral Researcher

CONSCIENTIOUS MORAL AGENT

Rachels J (2003)

Cape Peninsula University of Technology

creating futures

The Earth is 4.6 billion years old

Scaling to:
46 years

Humans have been on Earth for 4 hours

Our Industrial Revolution started 1 minute ago

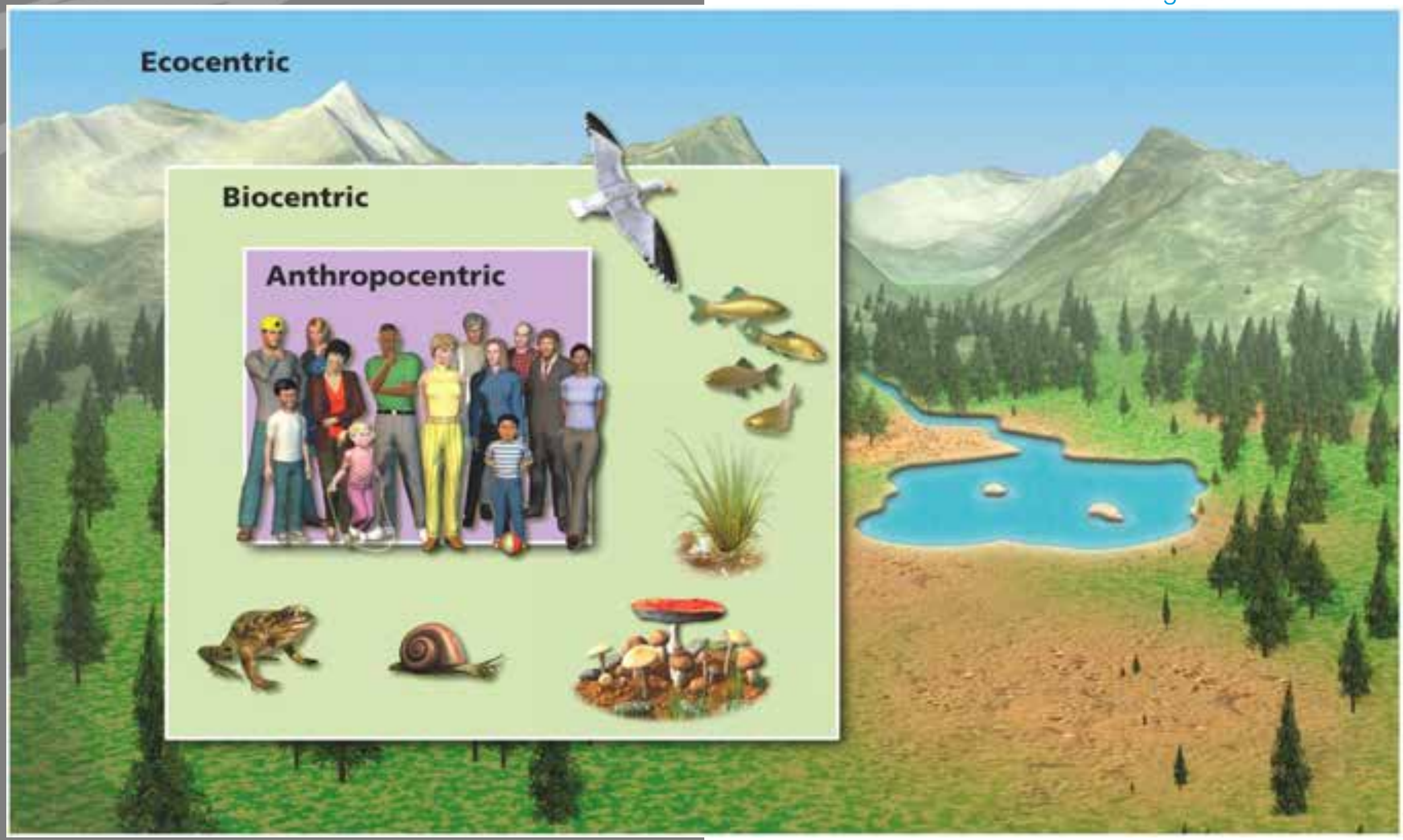
In that time, we've destroyed 50% of the world's forests

This is NOT sustainable

The classification of current worldviews

Cape Peninsula University of Technology

creating futures



RESEARCHER INTEGRITY

RESEARCH ETHICS

Cape Peninsula University of Technology

creating futures

RESEARCHER INTEGRITY

RESEARCH ETHICS

Cape Peninsula University of Technology

creating futures

Ethics: **moral** principles that govern behaviour or the conduct of activities

Integrity: the quality of having strong **moral** principles

Ethics: big **moral** picture
Integrity: personal characteristics.

Integrity is the critical connection between **ethics** and **moral** action

Cape Peninsula University of Technology

creating futures

Moral Theories of Ethics

- Virtue Ethics
- Consequentialism (Utilitarianism)
- Deontology
- Care Ethics

Cape Peninsula University of Technology

creating futures

Moral Philosophy as a Quest to Understand ‘THE GOOD’

- Understand goodness before you can be good

‘Good’ to describe the moral specifically

Describes human activity – usually that which affects another or others

Connected to other moral words – ought, right, just, duty, should

Cape Peninsula University of Technology

creating futures

Moral Philosophy based on: CONSEQUENCES

Decision on acting *morally* because of the *Consequences*

Utilitarianism

Moral rightness linked to the outcome of maximum value, benefit or happiness from the action

Cape Peninsula University of Technology

creating futures

Moral Philosophy based on:

DUTY

Deontology

- Moral rightness is not and should not be linked to the consequences of the action, but on acting according to rules and perceived duty.

Cape Peninsula University of Technology

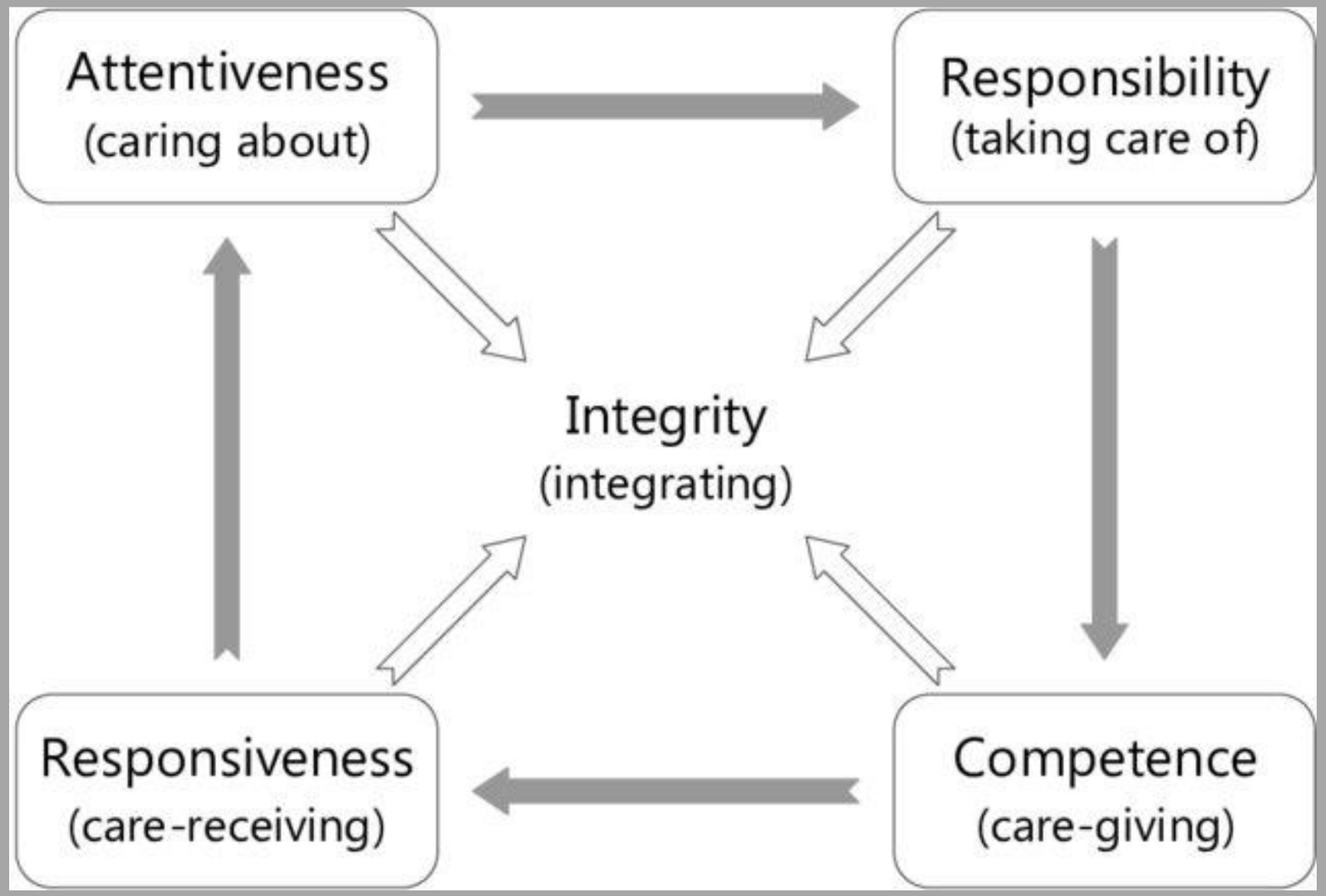
creating futures

Ethics of Care

Care as a practice (virtuous disposition)

4 elements of care:

1) attentiveness to become aware of need;
2) responsibility, respond and take care of need
3) competence, provide good & successful care;
4) responsiveness, to the position of others



Ethics in Engineering Students' Design Considerations: Case Studies of Electric Power Systems for the "Developing World" Mr. Ryan C. Campbell, University of Washington

Cape Peninsula University of Technology
creating futures

- **Beneficence** (benefit vs risk & provide benefit)
- **Non-maleficence** (avoid harm)
- **Respect for autonomy** (respect the person)
- **Justice** (fairness in distribution of benefit and risk)

Beauchamp T & Childress J (1994) The 'four principles' approach. In, *Principles of Health Care Ethics*. Chichester, John Wiley

ETHICS OF A SOCIETY

Ideas and beliefs: **Right or Wrong, Good or Bad Character**

Conceptions: **Satisfactory Social Relations and Attitudes**

Patterns of Behaviour: Social harmony, Justice, Fairness

Cape Peninsula University of Technology

creating futures

African moral language – character and moral personhood

Ethics of **Duty** (not of rights) and **Common Good** (social well-being)

To be a person:

- Honest
- Generous (universal hospitality)
- Compassionate
- Humble
- Peaceful
- Respect for others

Cape Peninsula
University of Technology

creating futures

The greatest happiness and good of tribe:

Altruism

Utilitarian

Social Ethics

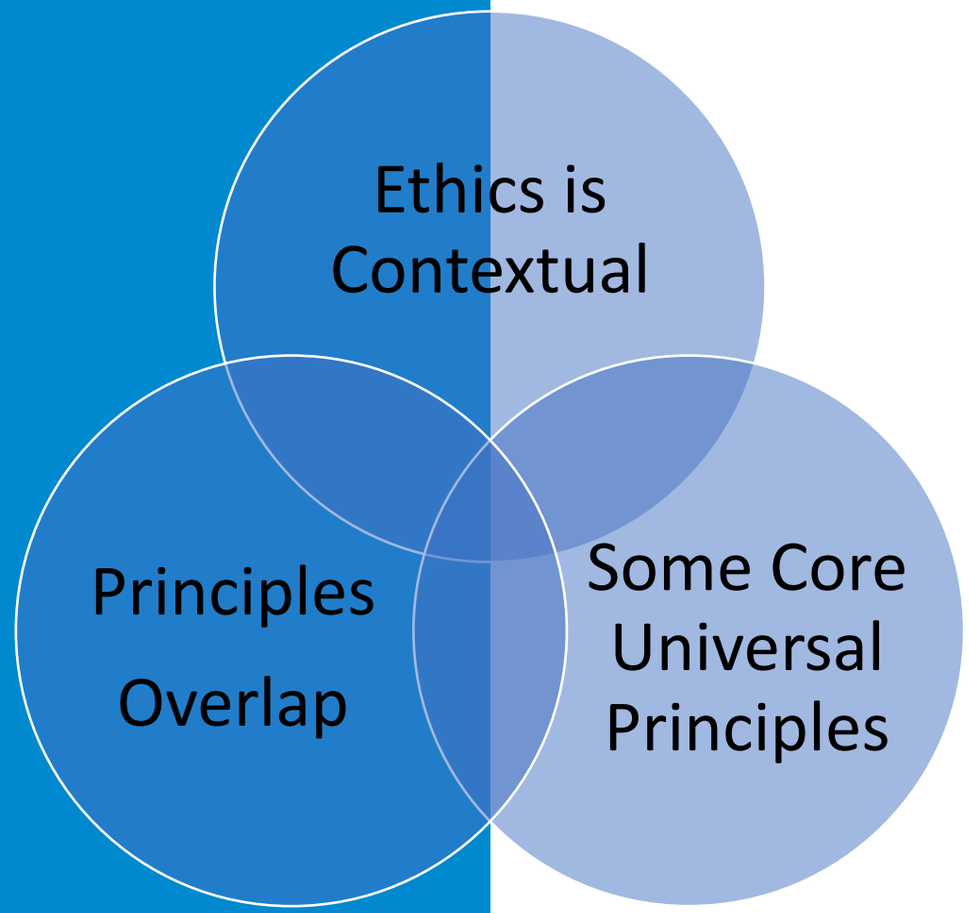
Cape Peninsula
University of Technology
creating futures

The common good

Cape Peninsula University of Technology

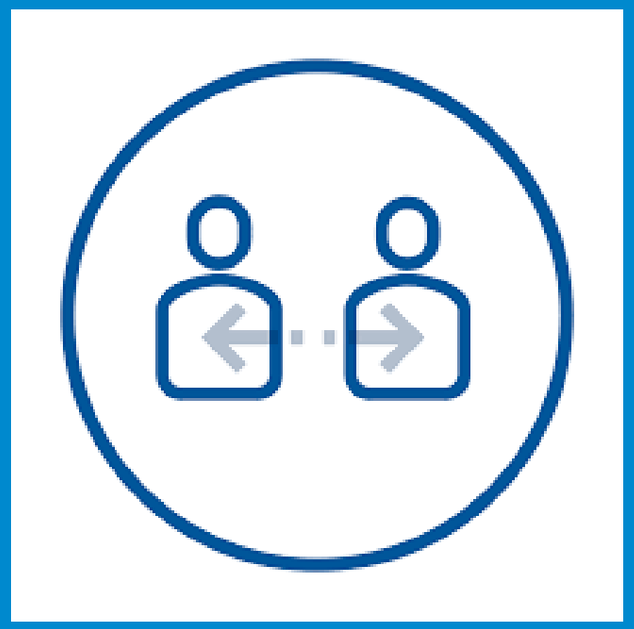
creating futures

Key Points



Code of Conduct for Researchers

Good Practice Guide for Researchers



Establishes a conceptual framework for researchers in a given context to ensure compliance with accepted behavior

Based on five fundamental principles of ethics:

Integrity

Rigour and Good Science

Professional Competence and Due Care

Confidentiality

Professional Behavior

CODE of CONDUCT (Professional)

Cape Peninsula University of Technology

creating futures

ECSA

Engineers must perform under a standard of professional behavior that requires adherence to the highest principles of ethical **conduct**. ... **Conduct** themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession.

What are the five codes of ethics?

- Integrity.
- Objectivity.
- Professional competence.
- Confidentiality.
- Professional behavior.

CODE of CONDUCT (Researcher)

Cape Peninsula University of Technology

creating futures

WHAT THE CODE COVERS (WHO)

- Research standards
- Research training and supervision
- Conflict of interest and bias
- Managing collaboration in research
- Financial management of research
- Quality management in research
- Managing and monitoring research data
- Peer review
- Intellectual property and authorship
- Publication and dissemination of research findings

CODE of CONDUCT (Researcher)

Cape Peninsula University of Technology
creating futures

GLOBAL CODE OF CONDUCT for Research in Resource-Poor Setting

Equitable Research Partnerships
(Including SASI, Wits, UCT, UNESCO …)
www.globalcodeofconduct.org/

Research partnerships between high-income and lower-income settings:
Advantages to both or Ethics dumping

FAIRNESS
RESPECT
CARE
HONESTY

Cape Peninsula University of Technology

creating futures

CODE of CONDUCT (Protection of Personal Information Act)

POPIA

ASSAf

Developed a Draft **Code of Conduct** for researchers in South Africa to comply with POPIA.

Introduction to Law

Cape Peninsula University of Technology
creating futures

Common Law: Case law
Statute Law: Defined by Acts

Public Law: Involves state/goverment
Private Law: Civil law

BASIS FOR COMPARISON	LAW	ETHICS
Meaning	Systematic body of published rules and regulations that governs the whole society and the actions of its individual members e.g. POPI Act	A branch of moral philosophy that guides people about the basic human conduct through guidelines e.g. Helsinki Declaration; DOH 2015
Governed By	State	Individual and Professional norms/codes of conduct (legal)
Binding/Violation	Legally binding. Violation of law may result in punishment e.g imprisonment or fine or both. POPIA: Fines, Civil Action, Imprisonment	Not binding and no legal punishment for violation of ethics. Can be consequences e.g. paper withdrawn, research suspended, institutional disciplinary process
Objective	Created with intent to maintain social order and to provide protection to all the citizens (including Privacy Protection)	Ethical guidelines are in place to help people to decide what is right or wrong and how to act

Existing legal frameworks governing personal information (research)

Cape Peninsula University of Technology
creating futures

Constitution of South Africa (right to privacy & safeguarding personal information)

Bill of Rights: 'everyone has … the right not to be subjected to medical or scientific experiments without their informed consent'

PAIA: Promotion of Access to Information Act (2000) - Manual

National Health Act (Health Research: NHREC)

DoH Guidelines 2015 on Ethics in Research

- Informed consent of the individual involved for research projects that involve human participants
- Health ethics committees to be registered with the NHREC

International standards: open science and data protection law in the African Union and European Union (GDPR)

POPI Act or POPIA

Cape Peninsula University of Technology

creating futures

Promulgated by Parliament
19 November 2013

The President of South Africa proclaimed the POPI commencement date to be 1 July 2020

Grace Period

Compliance to POPIA must be met from 1 July 2021

PROTECTION OF PERSONAL NFORMATION ACT (POPIA)

Cape Peninsula University of Technology
creating futures

Informed by General Data Protection Regulation (GDPR) of the EU

Minimum Requirement for Lawful Processing of Information

Implications for Research & Research Ethics

Cape Peninsula University of Technology
creating futures

Abbreviations & Explanations

PI:	Personal Information of Natural or Juristic Persons that if disclosed would reveal identity of individual
PR:	Personal Party (University)
Data Operator:	Person Processing Information
IR:	Information Regulator
IO:	Information Officer (VC at CPUT)
DIO:	Deputy IO (Registrar at CPUT)

Data Subjects

Cape Peninsula University of Technology
creating futures

The person or entity to which the personal information relates.
In research data subjects are:

- **Research participants**

And potentially

- **Research Sites.**

What is Personal Information?

Cape Peninsula University of Technology
creating futures

- **Demographic information**

(race, marital status, language, religion etc)

- **Background information**

(educational, financial, employment records)

- **Contact information**

(Twitter handles, physical address etc.)

- **Biometric information**

(fingerprints, voice recognition, retinal scans)

- Usernames and passwords
- Private correspondence
- Criminal record
- Opinions and preferences

Special Personal Information?

Cape Peninsula University of Technology
creating futures

Some categories of personal information require **extra care**.

- The information of minors
- Religious or philosophical beliefs
- Trade union membership
- Criminal behaviour
- Race or ethnic origin
- Sexual information
- DNA
- Political opinions

What Activities are Affected?

Cape Peninsula University of Technology
creating futures

The POPI Act has an impact on **everything** we do **with personal information** throughout the information life cycle:

1. Collection
2. Use
3. Share
4. Further Processing
5. Storage/Retention
6. Destruction

We need to understand and apply POPIA rules relevant to each stage in the research process.

Cape Peninsula University of Technology

creating futures

POPIA Does not Apply

- Household activities
- De-identified Information
- Processed by Public Body
- Journalistic, literary (CoC)
- Exemptions

POPIA Speaks to a Code of Conduct (Chapter 7)

Cape Peninsula University of Technology
creating futures

Purpose:
To provide legal and practical guidelines on the interpretation of POPIA in the research sector.

ASSAf has developed a Code of Conduct (Researchers)
To Information Regulator late 2021
Draft published and 13 weeks to comment
Expect imminently

8 conditions for processing personal information

(1) **Accountability**: Compliance ensured (Section 8).
(2) **Process limitation**: Lawful Basis (Section 9-12)
(3) **Purpose specification**: Defined purpose (Section 13-14)
(4) **Further processing limitation**: Re-use of information (Section 15)
(5) **Information quality**: Accurate & Up-to-date (Section 16)
(6) **Openness**: Transparency with Participant (Section 17-18)
(7) **Security safeguards**: Prevent data breach (Section 19-22)
(8) **Data subject participation**: Right of access/correct/delete (Section 23-2

How to treat information related to persons/companies/entities
Consent
Informed
Withdrawal

What the Code of Conduct covers

How the 8 conditions for processing personal information are understood for research

- Interpret
  - ❖ Exemptions (public interest)
  - ❖ Exceptions
  - ❖ Exclusions (de-identified)
- Use of social media data in research
- Information matching programmes in research
- Processing genetic data
- Cross-border data transfers
- Security safeguards
- Prior authorisations
- Governance and review of the Code of Conduct

Cape Peninsula University of Technology
creating futures

Core Focus of POPIA in a Research Context

Cape Peninsula University of Technology
creating futures

- Ensure that **if** personal identifiers **must** be collected, they need to be stored in a **secure, access-controlled** location to prevent the data being appropriated and used by third parties.
- POPIA does not prevent **open data sharing.** If personal identifiers are removed from shared datasets this complies with the Act.
- POPIA impacts the research process e.g.

❖ Storing only **de-identified datasets** on cloud storage

❖ Ensuring that on-site storage (PC hard drives, external hard drives, laptops) are strictly **access-controlled** for data protection.

THINK
What data and How to store!

Complaints Handling Procedure

Cape Peninsula University of Technology
creating futures

Complainant must first take the case to the **Responsible Party** at the **institution** (**Information Officer** investigates and can refer to/consult with the **REC** that approved the study)

complainant can take complaint to **ASSAf** who will appoint an **independent adjudicator** to review the case.

ASSAf can refer the case to the **NHREC** if it is better suited under their mandate and jurisdiction e.g. health research, registered REC.

complainant can take their case to the **Information Regulator** (National Body)**.**

Cape Peninsula University of Technology

creating futures

Useful Reference Website

https://popia.co.za

Cape Peninsula University of Technology

creating futures

Risk : Benefit Analysis

1.What are the risks?
2.How likely are the risks to happen?
3.What are the benefits?
4.How likely are the benefits to happen?

Cape Peninsula University of Technology

creating futures

Elements of Informed Consent

- Competence to act
- Thorough disclosure received
- Disclosure understood
- Voluntary action
- Consent to participate

Cape Peninsula University of Technology

creating futures

Shifts in Informed Consent

- From ***a responsibility to disclose***

  To ***quality participant understanding***
- From ***reducing, risk, harm, exploitation***

  To ***protection of autonomous choice***
- From ***paternalism and authority***

  To ***a relationship of equals***
- From ***doing a task***

  To ***engaging with a process***

RESEARCH MISCONDUCT

Cape Peninsula University of Technology

creating futures

3 Types of Research Misconduct

Fabrication

Falsification

Plagiarism

Conflict of Interest in Research

A **conflict of interest in research** exists where an individual may preference, or be perceived to preference, their own interests or obligations over their duties and responsibilities as a researcher.

Cape Peninsula University of Technology

creating futures

Conflict of Interest
(financial and non-financial benefits)

Actual

Potential

Perceived

Prevent Conflict of Interest in Research

Cape Peninsula University of Technology

creating futures

Avoid and/or Minimise Conflict

Disclose our Interest/s

Manage Conflicts

Keep Learning