Topic

RESEARCH ETHICS: A COMPREHENSIVE GUIDE FOR MASTERS AND DOCTORAL STUDENTS

TEACHING TUESDAYS
Prof Pumela Msweli, PhD
November 2020

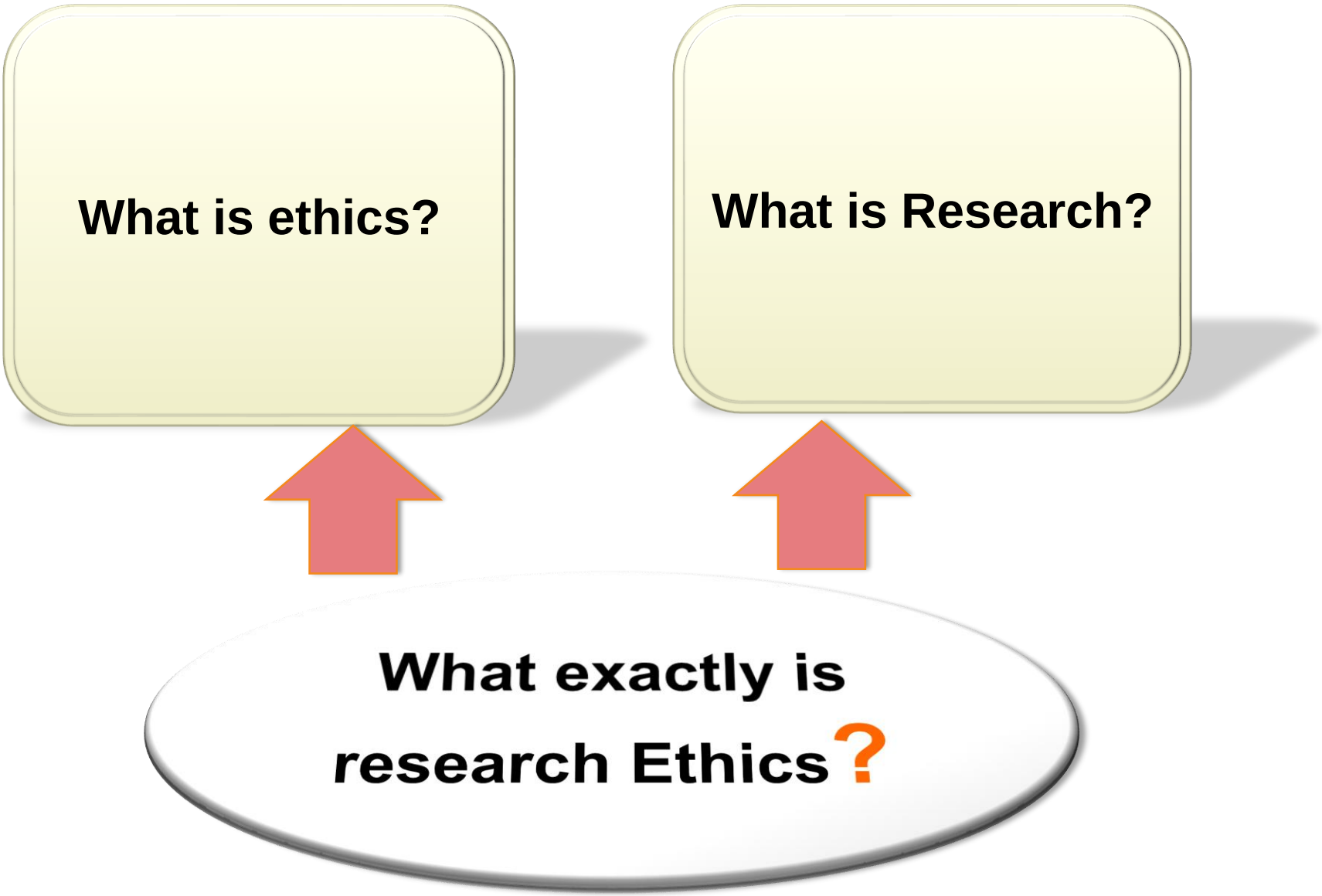
Building leaders who go beyond

TOPICS COVERED

1. What exactly is Research Ethics?
2. Scientific Research: Social vs Clinical Research?
3. Why be concerned with research ethics?
4. Development and Evolution of Research Ethics, Codes and Regulations: International Landscape

TOPICS COVERED CONT'D

6. Research Ethics Policies and Regulations: South African Landscape
7. What members of the Research Ethics Committee look for in your ethics proposal
8. How to submit a proposal for ethical clearance
9. Course evaluation



ETHICS DEFINED

- A discipline dealing with what is proper course of action for man (Aristotle, *cit in* Mckeon,1941)
- A branch of philosophy that looks at what is good and what is bad
- A system of obligation that we have towards others
- Also known as moral philosophy, involves, systematising, *defending*, and *recommending* concepts of right and wrong behaviour *(www.iep.utm.edu/ethics)*
- *A study of principles guiding the good of the individual within the context of social interactions and the community*

ETHICS DEFINED

ETHICS AS A THEORETICAL ENTERPRISE

Meta Ethics: "*is a branch of analytic philosophy that explores the status, foundations, and scope of moral values, properties, and words"* *Source:* https://www.princeton.edu/~achaney/tmve/wiki100k/docs/Meta-ethics.html

Normative Ethics: addresses the question of 'What ought to be done?' Normative Ethical theorists (Socrates, Kant, Stuart, Bentham) seek to provide action guides and codes.

Applied Ethics: domain specific ethics (Business, biomedical; APA, engineering, etc.)

ETHICS EVOLUTION

Aristotle (384-322 BC) – proposed a theory of virtue

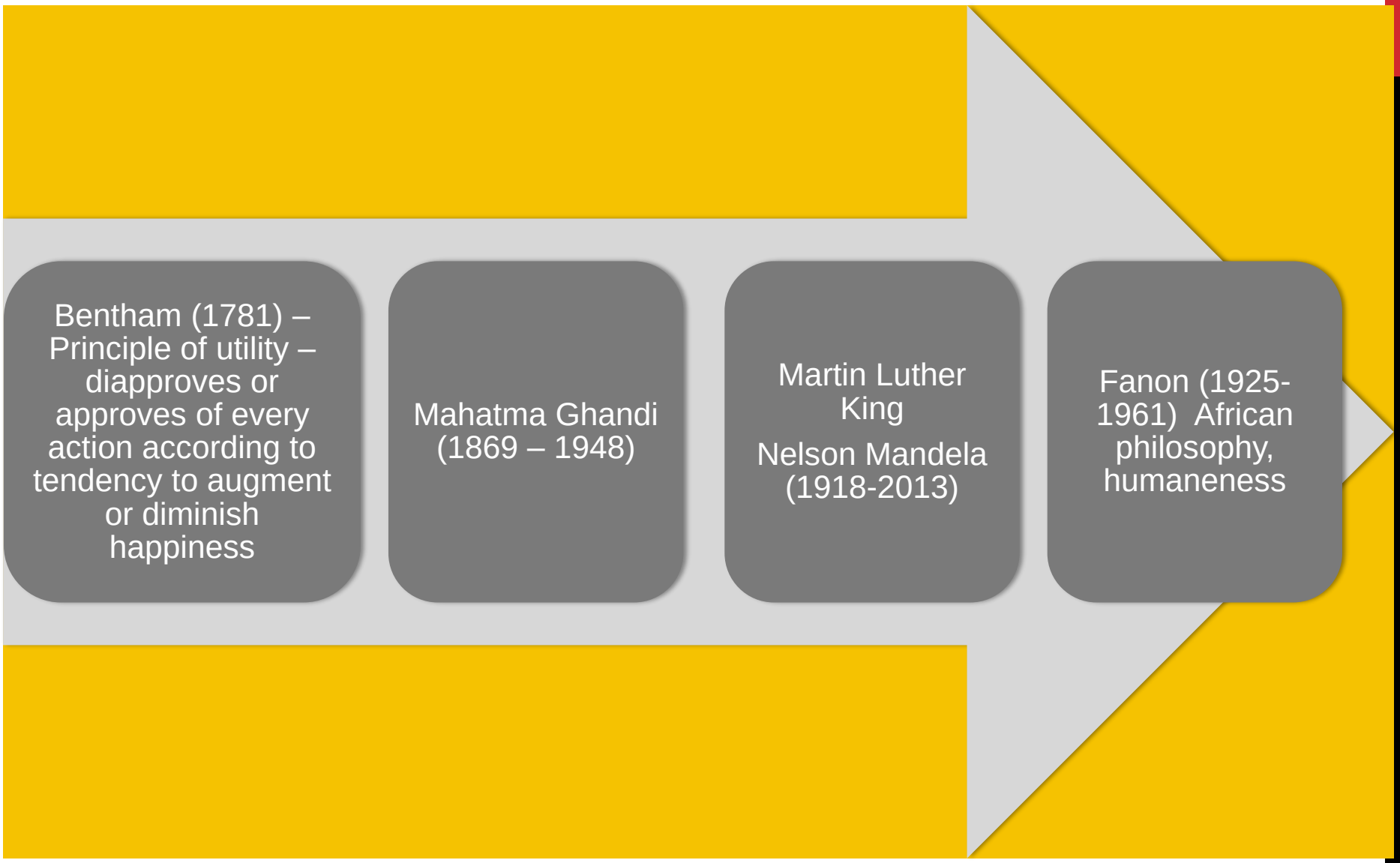
Socrates (469-399)

Siddhartha Gautama (563-480 BC)

Kant (1724-1804)

rightness of an action is determined by the character of the principle that a person chooses to act upon

ETHICS EVOLUTION



Generalisability of findings: the extent to which the sample used in the research project reflects the broader population of interest

Scientific Rigour (truth is accepted if there is sufficient evidence to support claims made through the research process. Such claims have to withstand the scrutiny of repeated testing)

Univesality and objectivity (explicit rules and systematic procedures)
- Research should be designed in a manner that allows any competent researcher to conduct a similar study and generate the same findings

Originality of research work: original ideas backed with appropriate evidence in a clear, logical and convincing argument that illustrates critical and analytical thinking.

Research Ethics therefore are:

1. A code of guidelines on how to conduct scientific research in a morally acceptable way.

2. Principles and standards that help researchers to uphold the value and standards of knowledge construction.

ETHICAL CONSIDERATIONS IN THE RESEARCH PROCESS

Ethical considerations come into play at six stages of research

1. Conceptualisation and design of the study (scientific merit, identify risks and ways to mitigate the risks)
2. When participants are recruited (the process of informed consent, right to privacy)
3. During the intervention or measurement procedure to which participants are subjected (management of risk)
4. In the release of results obtained
5. (protection of confidentiality and anonimity)
6. After the release of results (ensure that participants and communities involved in the research benefit)

ANOTHER WAY OF LOOKING AT RESEARCH ETHICS IS BY LOOKING AT UNETHICAL RESEARCH CONDUCT

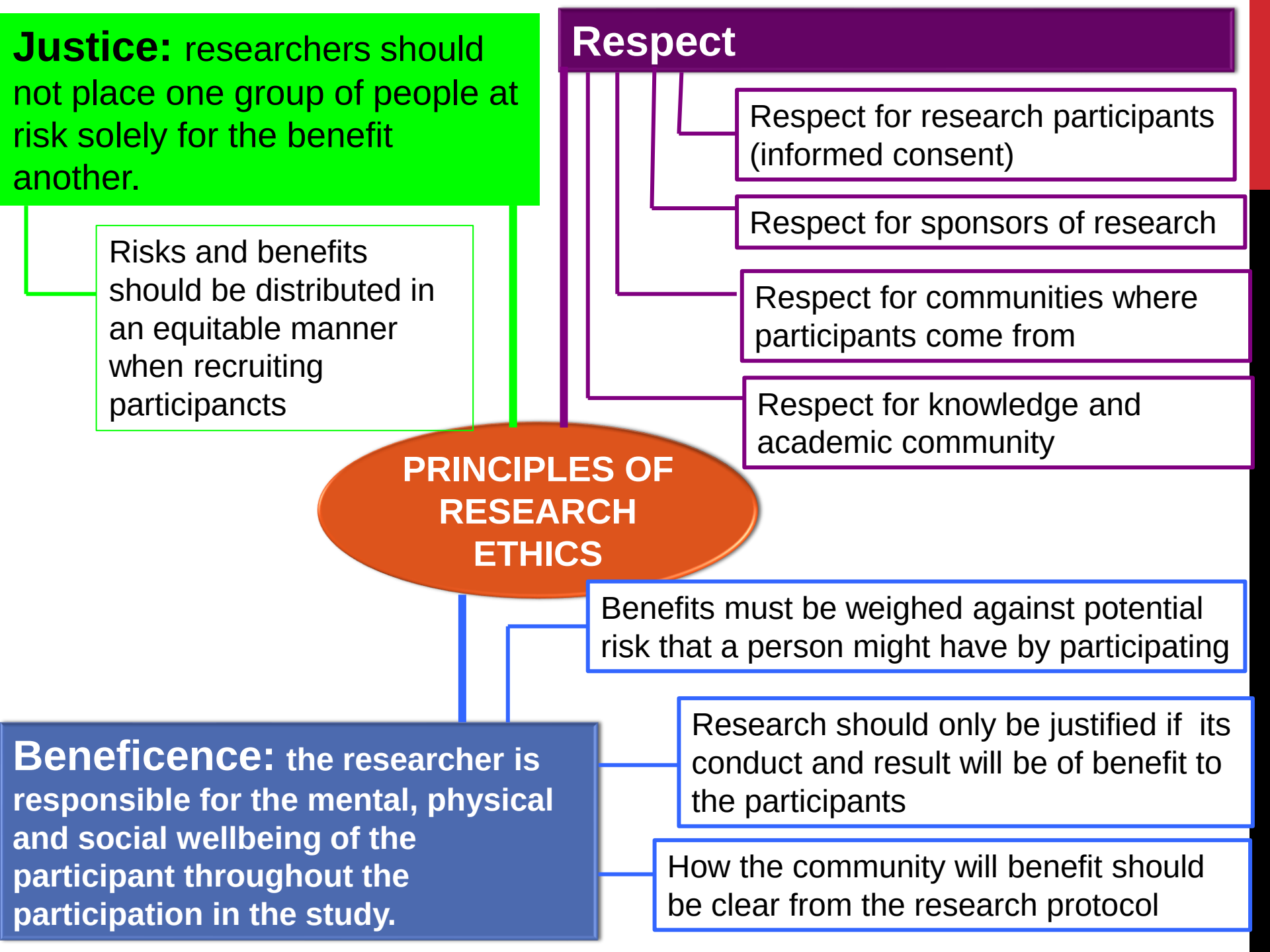
- **Deception (issues of full disclosure)**
  - Withholding information about the aim of the study
  - Misleading participants about the risks inherent in participating in the study
- **Plagiarism**
- **Conducting research that does not have a scientific base (ill-formed problem statement)**
- **Lack of objectivity and integrity in the design and conduct of research**
  - Not identifying the methodological constraints of the study that determine the validity of the findings
  - Misinterpretation of results
  - Not providing details of theories and methods that might be relevant in the interpretation of research findings
- **Fabrication or falsification of data**
- **Not following the appropriate ascription of authorship to a publication**

ANOTHER WAY OF LOOKING AT RESEARCH ETHICS IS BY LOOKING AT UNETHICAL RESEARCH CONDUCT

- **Not respecting the right to privacy**
- **Not respecting the right to anonymity and confidentiality**
- **Not respecting rights of vulnerable groups**
  - Children
  - Mentally handicapped individuals
  - The aged
  - Prisoners
  - Illiterate
  - Those with low social status
- **Not having due consideration for the environment**

FUNDAMENTALLY RESEARCH ETHICS ARE:

- a way of conducting the research enterprise such that the three fundamental principles of research (respect, beneficence and justice) are upheld.
- Ethical research must conform with the national and international accords and prescripts.


Justice: researchers should not place one group of people at risk solely for the benefit another.
Risks and benefits should be distributed in an equitable manner when recruiting participancts
Respect
Respect for research participants (informed consent)
Respect for sponsors of research
Respect for communities where participants come from
Respect for knowledge and academic community
PRINCIPLES OF RESEARCH ETHICS
Benefits must be weighed against potential risk that a person might have by participating
Beneficence: the researcher is responsible for the mental, physical and social wellbeing of the participant throughout the participation in the study.
Research should only be justified if its conduct and result will be of benefit to the participants
How the community will benefit should be clear from the research protocol

DIFFERENCE BETWEEN CLINICAL AND SOCIAL SCIENCE RESEARCH

	Clinical Research	Social Science Research
Definition	A research study intended to test safety, quality, effectiveness of new and/or existing or old medicines, medical devices and/or treatment options, using human participants (SA – GCP Guidelines, 2006)	A systematic recording and analysis of data that may lead to generaliseable, principles and theories resulting in prediction and possibly management of behaviour and events in society.
Research activities	Invasive and non-invasive procedures that may include surgical untervention, removal of body tissues/ fluids, administration of chemical substances, observation, administration of questions etc.	Review of literature, review of data, interviews, focus groups, observatations, administration of survey instruments, or tests etc.
Phases or steps followed	Four phases	More or less eight phases (depending on research questions and design of the study)

PHASES OF RESEARCH: CLINICAL VS SOCIAL

CLINICAL TRIALS	SOCIAL RESEARCH
PHASE I: A new drug, vaccine or medical device is tested in a small group of healthy persons for the very first time. The aim is to determine the general safety, the correct dosage and negative effects.	**PHASE 1:** Problem identification
PHASE II: Clinical trials the new drug, vaccine or medical device in a larger group (several hundred people)	**PHASE2:** Problem definition
PHASE III : testing to several thousand people	**PHASE 3:** Development of a theoretical framework
PHASE IV: clinical trials done to several thousand people after the new drug, vaccine or medical drug has been registered and licensed for sale by the Medical Control Council	**PHASE 4:** Hypothesis formulation or literature review
	PHASE 5: Research Design
	PHASE 6: Data collection
	PHASE 7: Data analysis
	PHASE 8: Report writing and dissemination of findings

WHY BE CONCERNED WITH RESEARCH ETHICS?

1. **Professional Responsibility**
2. **To avoid reputational damage**
3. **Research can be harmful to:**
   - Participants
   - To researchers
   - To institutions
   - To research communities
4. **To avoid litigation**
   - In a scenario where a proposal is classified as Ethics Category 1 (exempt from Ethics and Biosafety Research Committee Review) liability and responsibility arising from decisions based on ethics are shouldered by the FRC and its members.

EVOLUTION OF RESEARCH ETHICS, CODES AND REGULATIONS: INTERNATIONAL LANDSCAPE

Berlin Code
(1900)
Much emphasis on Beneficence and Autonomy

Guidelines for Human Experimentation
(1931) Focus on therapeutic vs nontherapeutic informed consent

Nuremberg Code
(1947)

Declaration of Helsinki
(1964)

Belmont Report
(1978)

Council for International Organisations of Medical Science (CIOMS) Guidelines
(1982)

International Conference on Harmonisation
(1990)

NUREMBERG TRIAL 1947: precursor to Nuremberg Research Ethics Code

23 people were tried (20 doctors and 3 administrators). Seven were sentenced to death by hanging; nine were given prison terms and seven were found not guilty.

Source: history.com Editors
URL: https://www.history.com/topics/world-war-ii/nuremberg-trials

NUREMBERG CODE

The judgement by the war crimes tribunal at Nuremberg Germany, laid down ten standards to which physicians must conform when carrying out experiments on human subjects.

Key principles in the Nuremberg Code:

- Voluntary consent of the human subject – capacity to consent, freedom from coercion and an understanding of risks and benefits involved; and freedom to bring the experiment to an end.
- Minimisation of risk and harm.
- The science and design of the study must yield fruitful outcomes.

Declaration of Helsinki (1964)

1964 Adopted by the World Medical Association

Ten out of the 12 ethics research markers from the Nuremberg Codes were adopted.

The central point in DoH is the principle that the well-being of the participant should take precedence over the interests of science

Photo credit: http://www.pachd.com/free-images/helsinki/market-square-01.jpg

First Revision to the DoH adopted in Tokyo in 1975

- The revised DoH was drafted by three Scandininavian professors of medicine
- The key addition was the requirement that independent committees review research protocols
- Informed consent requirements were simplified for non-therapeutic research
- The document was an elaboration of the1964 version

Photo credit: http://www.dreamstime.com/free-photos-images/tokyo-images.html

Second Revision to the DoH adopted in Venice in 1983

- Minor revision were made to the document adopted in Tokyo in 1975 (for example, the word “doctor” was changed to “physician”

Photo by Peter Velei:
http://www.islands.com/files/_images/201006/Venice_Italy_calender_wallpaper_1920x1200.jpg

Third Revision to the DoH adopted in Hong Kong in 1989

- The key addition to the document was the requirement to submit the protocol to a specially appointed committee independent of the researcher.

Photo by Sean Pavone: http://www.123rf.com/photo_18193986_rainbow-bridge-spanning-tokyo-bay-with-tokyo-tower-visible-in-the-background.html?term=tokyo%20city

BELMONT REPORT – OUTCOME OF THE TUSKEDEE CASE

- As a result of the Tuskedee case the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research was established
- The report sets forth the principles underlying ethically acceptable conduct of research involving human participants.
- Report is also the basis for the US Federal Regulations governing research
- The Belmont report emphasises on the principles of **respect, justice, and beneficence.**

SOUTH AFRICAN HUMAN RESEARCH ETHICS REGULATIONS

Act No 108 of 1996 – The Constitution of the Republic of South Africa Section 12 (2)(b) & (c)

"*Everyone has the right to bodily and psychological integrity which includes the right (b) to security and control over their body and (c) not to be subjected t medical or scientific experiments without their informed consent*

Other rights guaranteed in the Constitution that are applicable to the rights of research participants include: right to dignity, privacy, access to health care

REGULATORY FRAMEWORK AND STANDARDS FOR CLINICAL TRIALS IN SOUTH AFRICA

All clinical trials must have approval from the Medicines Control Council (MCC)

INFORMED CONSENT
Requirement enshrined in the Constitution and in the National Health Act (2003) and in the GCP guidelines

All clinical trials must be registered with the South African Trial Register

Clinical trials should be conducted in accordance with ethical principles that have their origin in the **Declaration of Helsinki** and are consitent with the country's GCP guidelines

INFORMED CONSENT

- A consent given by well informed potential participants about the nature of the research procedure, scientific purpose,and about the risks and benefits of the study.
- Informed consent is given without subjecting the potential participant to coercion, intimidation or undue influence
- Participant's understanding of the research aim and objectives must be addressed by laying out the details out in the language the participant understands, in a culturally acceptable way.

STAGES AND PROCESS OF INFORMED CONSENT

Stages of informed consent	Informed Consent Activities
Before the commencement of the study	❖ Assessment of the local culture ❖ Identification of risks and benefits before and after the study ❖ Pilot testing
At the beginning of the study	❖ Information is presented with the aid of support material to enhance understand of the research aims and objectives ❖ Risks and benefits of the study are presented ❖ Understanding is assessed
During the study	❖ Reinforce key ethical principles ❖ Address issues of concern

KEY ELEMENTS OF INFORMED CONSENT

- Description of research aims and objectives
- Description of potential risks
- Description of expected benefits
- Explanation of confidentiality and anonymity of participants
- Explanation of participants rights including the fact that participation is voluntary
- Explanation of issues relating to remuneration/compensation for injuries

WHAT MEMBERS OF THE RESEARCH ETHICS COMMITTEE LOOK FOR IN YOUR ETHICS PROPOSAL

WHAT THEY CHECK	HOW THEY CHECK IT
1. Respect and Dignity of participants	• Appropriate information to participants in a form and language they understand • They check that there is a fair and humane way by which consent will be obtained • They check the type and nature of questions that participants will be required to respond to • Check if the questions are culturally correct and sensitive to the value systems of the participants • Check that the rights of vulnerable persons are protected and South African regulations with respect to vulnerable participants are complied with
2. Privacy and confidentiality	• Check for a declaration that guarantees protection of the participant's privacy and confidentiality
3. Favourable balance of benefits and risks	• Check if proposal has outlined potential harm (psychologically, legally or economically), and measures that will be taken to ameliorate potential risks. • Check whether the direct benefit of the research has been

WHAT MEMBERS OF THE RESEARCH ETHICS COMMITTEE LOOK FOR IN YOUR ETHICS PROPOSAL

WHAT THEY CHECK	HOW THEY CHECK IT
Fair subject and community selection	❖ Research must not exclude a class of people who are likely to benefit from research participation or in whom the results of a specific kind of research are likely to be applied. ❖ The sampling plan of the research project must be checked for fair subject selection.
Professional competence and sufficient capacity	❖ A Principal investigator according to the GCP (SA) carries the primary responsibility for securing participants' safety and well being during the study.
Coercison, undue pressure and conflict of interest	❖ A researcher must disclose the source and extent of funding to research participants. ❖ Commercial affiliations or financial interests at the time of proposing and reporting the research must be disclosed.
Research involving minors and vulnerable persons	❖ The researcher should demonstrate an awareness of applicable national and international laws, regulations and codes (eg Act No 38 of **2005** The South African Children's

HOW TO SUBMIT A PROPOSAL FOR ETHICAL CLEARANCE

The proposal submitted for ethical approval should demonstrate that each of the following ethical aspects arenot only addressed, but are discussed in a logical and cogent fashion:

1. Respect and dignity of participants
2. Privacy and confidentiality
3. Balance of benefits and risks
4. Sampling plan – fair participant selection
5. Competence and capacity of researcher
6. Protocols and procedures followed in dealing with minors, vulnerable persons (if applicable)

REFERENCES

1. Azenabor G. 2008. The Golden Rule Principle in an African Ethics, and Kant's Categorical Imperative. An African Journal of Philosophy, XX!: 229-240.
2. Belmont Report. Available at http://ohsr.od.nih.gov/guidelnes/belmont.html
3. Center for Disease Control and Prevention, 2014. US Public Health Service Syphillis Study at Tuskegee http://www.cdc.gov/tuskegee/timeline.htm
4. Declaration of Helsinki, World Medical Association, 2008. Available at: http://www.wma.net/en/30publications/10policies/b3/index.html
5. Ethics in Health Research: Principles, Structures and Processes available at: htttp://doh.gov.za/docs/index.htm)
6. Guidelines for good Practice in the Conduct of Clinical Trials in Human Participants in South Africa, available at: http://www.doh.gov.za/docs/policy/trials contents.htm
7. International Ethics Guidelines for Biomedical Research Involving Human Subjects, CIOMS, 2002. Available at: http://www.cioms.ch/frame_guidelines_nov_2002.htm
8. McKeon R. (Ed) 1941. The Basic Works of Aristotle. Random House Inc.
9. Grodin MA. "Historical origins of the Nuremberg Code". In: *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*. Annas, GJ and Grodin, MA (eds.). Oxford University Press, Oxford, 1992 Republic of South Africa, Government Gazette, 23 July 2004, vol.469, No 26595. National Health Act No 61 of 2003.