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The Emerging Ethical Terrain in Research

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Background to Research Ethics

- Research dealing with human subjects and animals is guided by International, Regional and National rules and regulations.
- The most important is the World Medical Association Declaration of Helsinki, The World Health Organization (WHO) and the Council for International organizations of Medical Sciences (CIOMS), Nuremberg and Belmont reports among others. (STISA, AU and UNESCO)
- In Kenya –National Commission of Science, Technology and Innovation (NACOSTI) under the Science and Technology Act, is mandated to coordinate all research in Kenya and advise the government on all matters related to research.





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The National Commission for Science, Technology and innovation

- **NACOSTI – Through the National board is mandated to regulate and assure quality in science, technology and innovation sector and advice the government accordingly.**
- **NACOSTI REGISTERS AND ACREDITS RESEARCH INSTITUTIONS IN KENYA (ISERCS)**
- The Regulations under the SCIENCE TECHNOLOGY & INNOVATION Act 2014 are provided in three legal notices :
- LEGAL NOTICE No. 106: Registration and Accreditation of Research Institutions Regulations, 2014
- LEGAL NOTICE No. 107: Relevance and Quality Assurance in Research Regulations, 2014
- LEGAL NOTICE No. 108: Research Licensing Regulations





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Introduction to the Centre for Research Ethics and Safety

The Centre for Research Ethics and Safety is established under the Division of Research, Innovation and Outreach with an expanded mandate to coordinate and oversee ethics in research protocols for human subjects, animal use and care and biosafety and biotechnology in compliance with ethical requirements and regulations internally, nationally, regional and internationally



The Role of Institutional Scientific Ethics Review Committees

ISERCS

- Review ethical concerns and clear research protocols with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants;
- Monitor the research study;
- Document procedures and prepare annual reports;
- Examine and ensure compliance with all regulatory requirements, applicable guidelines and laws.





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Some of the challenges facing this Process

- Inadequate policies and guidelines for research misconduct at the institutional level
- Threshold of proof that misconduct was committed intentionally
- An allegation of research misconduct is a lengthy process consist of several steps including: inquiry, investigation and recommendation.
- Some institutions do not report research misconducts for fear of losing credibility





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Policies/Guidelines Documentations





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HISTORY OF THE RESEARCH ETHICS MOVEMENT

Breaking and re-breaking of **bones** (to see how many times they could be broken before healing failed to occur) Nazi war crimes

Patients **injected** with live cancer cells (Jewish Chronic Disease Hospital, NY, 1963)





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HISTORY OF THE RESEARCH ETHICS MOVEMENT

400 men **left to suffer** with syphilis long after a cure (penicillin) was available. (Tuskegee, Alabama, 1932-72)

Milgram's study sustained no physical harm, they **suffered shame** and embarrassment for having behaved inhumanely toward their fellow human beings. (1963)





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HISTORY OF THE RESEARCH ETHICS MOVEMENT

Prisoners

Elderly persons who
speak only Jewish

Poor sharecroppers

Deception without
debriefing





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ANY KENYAN SCANDAL?

- How are we doing ?
- Is our research scientific?
- Is our research ethical?
- Are we protecting "Wanjiku", and the larger community?



SCANDAL 1

A children's home in Nairobi...

- In 2001, a bitter row erupted between the owners of a Nairobi HIV and Aids orphanage and a researcher at Kenya's Institute of Primate Research over blood samples which were allegedly collected from the minors and siphoned off to Oxford University in the UK. A researcher who exposed the scandal said the Director of the home had been bleeding HIV-positive children with the help of interns from the UK in exchange for money for the institution.

Kenyan patients being used as guinea pigs by researchers' September 10th 2013, By Peter Orenge.
Standard Media



SCANDAL 2

Majengo Sex Workers (SWs)

- The University of Nairobi & University of Manitoba in Canada researchers followed a group of sex workers in Nairobi. They remained HIV negative despite long exposure to HIV+ men. They were hoping to discover what kept the women HIV negative & use their findings to develop a HIV vaccine. The researchers worked there >15 yrs. Later, some women, thought to be immune to HIV became infected. Many argue that the women were exploited by researchers and had little to show for their contribution to science.

Kenyan patients being used as guinea pigs by researchers' September 10th 2013, By Peter Orenge.
Standard Media



SCANDAL 3

Cell phone data mining

- In an incident dubbed “Cellphone data mining breakthrough technology,” researchers at the Harvard School of Public Health & KEMRI admitted they used un authorized data to conduct a survey on how malaria spreads in Kenya without informing the participants. A statement posted on the university’s website stated between June 2008 and June 2009, the researchers mapped every call or text made by each of 14,816,521 Kenyan mobile phone subscribers.

Kenyan patients being used as guinea pigs by researchers’ September 10th 2013, By Peter Orenge.
Standard Media





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DEFINITION OF ETHICS

- Ethics from Greek word 'ethos' (character) The branch of knowledge that deals with moral principles.

What is Ethics???

- Many people say that it is the intellect which makes a great scientist. They are wrong: it is character

-Albert Einstein





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EXAMPLES OF VULNERABLE GROUPS



<https://www.wvi.org/our-work/health>



<https://theconversation.com/why-people-dont-get-emergency-medical-care-in-time-a-study-in-south-africa-141462>



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EXAMPLES OF VULNERABLE GROUPS



30 January 2026

1





Breastfeeding and mental health



What makes her vulnerable?

Mom Truth: Breastfeeding is hard

Breastfeeding puts a big part of the parenting load on ME and that's scary

I put a lot of pressure on myself about breastfeeding

When my baby cries it's even harder to figure out what I'm doing

Sometimes breastfeeding makes me feel like I'm on the clock

It didn't come as naturally as I expected

My nipples hurt and latching is hard


I don't feel like I know what I am doing

I didn't feel prepared for this

I feel like I'm feeding my baby all the time

People share a lot of opinions and most of them are not supportive

I'm often worried about if my baby is eating enough or is gaining enough weight



@psychedmommy





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THE BASIC PRINCIPLES OF ETHICS

THE INTEREST AND WELFARE OF THE INDIVIDUAL SHOULD
HAVE PRIORITY OVER THE SOLE INTEREST OF SCIENCE OR
SOCIETY

MAXIMISATION OF BENEFIT AND MINIMISATION OF
HARM TO HUMAN RESEARCH PARTICIPANTS AND
ANIMALS.





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BASIC PRINCIPLES OF ETHICS

THE RIGHT TO AUTONOMY AND INDIVIDUAL RESPONSIBILITY
AND SPECIAL MEASURES FOR THOSE NOT CAPABLE OF
EXERCISING AUTONOMY

THE NEED FOR PRIOR FREE AND INFORMED CONSENT OF THE
PERSON BASED ON ADEQUATE INFORMATION





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BASIC PRINCIPLES OF ETHICS

PRIVACY AND CONFIDENTIALITY.



THE ESTABLISHMENT OF INDEPENDENT, MULTIDISCIPLINARY AND PLURALISTIC ETHICS COMMITTEES IN ORDER TO ASSESS THE RELEVANT ETHICAL LEGAL SCIENTIFIC AND SOCIAL ISSUES RELATED TO RESEARCH PROJECTS INVOLVING HUMAN BEINGS.





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What are the Requirements for a Quality Study Proposal???





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THE PROCESS

What is a study protocol

Research Plan

Describes all steps of a study from
identification of the problem to application of
the results





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It should include all the information to answer the following questions:

- Is the research question relevant and important?
- Will the objectives answer the research question?
- Will the study design allow the objectives to be achieved?
- Is the power of the study sufficient?
- What will be the public health impact of the findings?





TITLE OF PROTOCOL SHOULD BE CLEAR

Examples of titles

- An open-label, multicentre, randomised, adaptive platform trial of the safety and efficacy of several therapies, including antiviral therapies, versus control in mild / moderate cases of COVID-19.

RE: Development of Allele Frequencies for The Kenyan Population Using Globalfiler[®] and Y-Filer[®] Plus Markers for Advanced Forensics (CBRD/PROP/197)





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Does the title tell what is expected ?

What is in a title?



When you will be mine





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INVESTIGATORS!!!!

The choice of investigator goes to whether they have the capability, experience and expertise to conduct the study.

The role and responsibility of the principal investigator should include training of co-investigators and key study staff.





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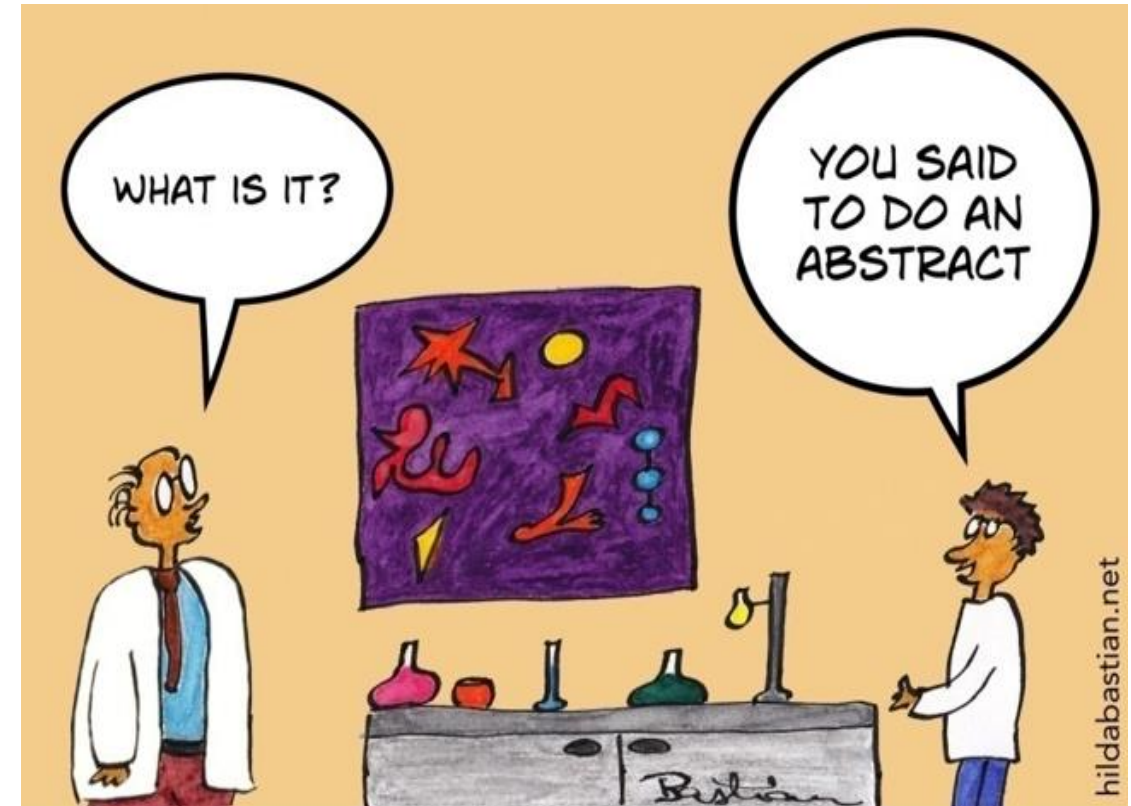
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THE ABSTRACT

The purpose of the abstract is to provide a bird's eye view of the study. If after reading the abstract it is not clear why, what and how the study is going to be carried out it may mean that the investigator is not clear about how the study will be carried out.





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LITERATURE REVIEW

- Gives the WHY of the study
- The Conceptual Framework and theories show the connectedness of the study
- After dealing with the what, ensure that the what is in line with the Why.
- The Why provides the social value of the study which lies in the principle of beneficence





PROTOCOL SUMMARY

LAY SUMMARY – GOOD EXAMPLE

- **Suicide is one of the most common causes of death in the United States. Older adults are at higher risk of suicide than all other age groups. Most people who die by suicide are depressed. However, most people who are depressed do not kill themselves. It is urgent that we learn more about what might make a depressed older person commit suicide. Studies have shown that genetics may be important.**
- **However, almost nothing else is known about the role of genetics in suicide. For example, we do not know if genetics are more important for men or women, or for young or old.**
- **This lack of information is a problem; we can only prevent suicide if we understand the risk factors.**
- **The current project will study suicide in Swedish twins.**
- **Twins born between 1886 and 1958 will be included. Information will come from several sources. These sources include questionnaires and hospital records. The researchers will also know which twins have died and how they died. The researchers will use statistical models to answer the research questions**

What is known

What is not known

The aim of the study

The methods that
will be used



Example

Study title: Warden SJ, Metcalf BR, Kiss ZS, et al. Low-intensity pulsed ultrasound for chronic patellar tendinopathy: a randomized, double-blind, placebo-controlled trial. *Rheumatology* 2008;47:467–71. **Research question:** How does low-intensity pulsed ultrasound (LIPUS) compare with a placebo device in managing the symptoms of skeletally mature patients with patellar tendinopathy? **Research hypothesis:** Pain levels are reduced in patients who receive daily active-LIPUS (treatment) for 12 weeks compared with individuals who receive inactive-LIPUS (placebo). **Objective:** To investigate the clinical efficacy of LIPUS in the management of patellar tendinopathy



OTHER KEY COMPONENTS FOR ETHICS CONSIDERATION

Validity/Scientific merit

- The research design must address specific research questions.
- Also, research ethics demands that the methods used must relate specifically to the research questions.
- Hence, the conclusions of the study must correlate to the questions posed and the results.





OTHER ETHICAL CONSIDERATIONS

Sampling/inclusion & exclusion criteria

- Sampling is the first step in [research design](#).
- You will need to explain **why** you want a **particular group** of participants. **(inclusion criteria based on the research question)**
- You will have to explain why you left out certain people or groups. **(Exclusion criteria based on the safety of the participants)**
- In addition, if your sample includes children or special needs individuals, you will have additional requirements to address like parental permission. **(Assent/proxy consent/surrogate consent)**

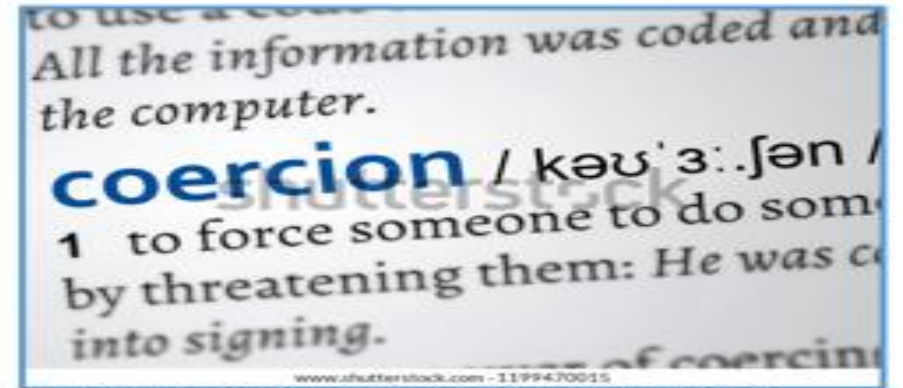




OTHER ETHICAL CONSIDERATIONS

Voluntary Participation and Consent

- An individual should at **no point feel any coercion** to participate in a study.
- This includes any type of **persuasion or deception** in attempting to gain an individual's trust.
- Informed consent states that an individual be **informed** of the study **before** they give their **explicit consent** to participate in the study.
- You can think of consent process as an **agreement of trust** between the researcher and the participants. (Fidelity)



<https://www.shutterstock.com/image-illustration/coercion-dictionary-word-vocabulary-page-600w-1199470015.jpg>





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SUMMARY OF ETHICAL CONSIDERATIONS

Privacy

A person's
right to
control access
to his or her
personal
information

Anonymity

The situation
in which
someone's name
is not given
or known

Confidentiality

The participant's
identity, personal
information,
responses, etc. will
not be disclosed to
anyone outside of
the research team
unless otherwise
agreed upon



THE DEVELOPING ETHICAL TERRAIN

1. Digital and Data Driven Research

- The digital revolution has transformed research across disciplines. Tools such as online surveys, mobile data collection, and big data analytics have made it easier to gather vast amounts of information, on the flip side however, but they blur traditional boundaries of privacy and consent.
- This puts the onus on the researchers to obtain meaningful consent when data is passively collected online, establish their obligations when using publicly available data, such as social media content as well as to consider issues of data security in an era of cloud storage and cross-border sharing.



2. Artificial Intelligence and Automation

- AI and machine learning tools are revolutionizing research from predicting trends in economics to analyzing medical images. These technologies can however also introduce bias, reduce transparency, and raise questions about accountability.
- Ethical AI research requires careful consideration of various factors such as algorithmic bias and fairness, data provenance and consent and responsibility when AI-generated insights impact people's lives or policy choices. Researchers must therefore go beyond compliance to actively audit and challenge bias within their models and datasets.





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3. Community Engagement and Social Justice

- Contemporary ethics is no longer limited to avoiding harm, but increasingly emphasizes beneficence and social impact. Research involving communities, especially in development or public policy contexts, should ensure that findings contribute to local well-being and empowerment.
- This requires early and continuous community consultation, effective feedback mechanisms after data collection as well as transparent sharing of outcomes with participants and stakeholders. Ethics, therefore, extends beyond the research process as it shapes how knowledge benefits society.



4. Cross Border Collaboration and Cultural Sensitivity

- Global research collaborations have expanded opportunities for innovation, but they also expose ethical tensions between diverse cultural norms, legal systems, and institutional standards. For instance, research practices acceptable in one country may be inappropriate in another.
- Moreover, power imbalances between institutions in the Global North and South can lead to inequities in authorship, funding, and access to results. Ethical research collaboration calls for mutual respect and equitable partnerships, clear agreements on data ownership and benefit-sharing and recognition of local expertise and priorities.





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5. Integrity Under Pressure

- Today's academic and professional environments often prioritize rapid publication, competition for funding, and high-impact results. This “publish or perish” culture can tempt researchers to cut corners, reuse data without consent, or misrepresent findings.
- Institutions must strengthen research integrity systems through training on responsible research conduct, mentorship and peer accountability and clear consequences for misconduct. Sustaining an ethical culture means rewarding transparency and collaboration as much as innovation.





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**A GOOD
BEGINNING
MAKES A
GOOD ENDING**

Proverb

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