

# Research in Health Sciences

Second Edition

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and F M Mulaudzi**



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## Preface

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Research is an essential part of both undergraduate and postgraduate programmes. Thus, knowledge of research designs and methods is critical for both these groups of students as well as emerging researchers in various disciplines. Undergraduate and postgraduate students should therefore stay up to date on developments in research design and methods to understand the published literature better and know which research designs and methods are appropriate depending on the situation or type of inquiry they are planning or engaged in.

Although there are a large number of books on research on the market, a noticeable gap is a book that takes different levels of researchers and context-specific guidance into consideration. With *Research in Health Sciences (2nd edition)*, we attempt to provide guidance related to research design and methods that are comprehensible. Researchers can initiate, formulate, conceptualise and execute their research more efficiently and holistically when they have a firm understanding of all the aspects comprising the research process and can apply the concepts underlying these.

This book is intended for novice researchers (honours and master's students) in Health Sciences (i.e., Nursing, Nutrition, Medicine, Pharmacy, Psychology and Social Work) and in disciplines like Theology, Humanities and Education, who need accessible, easy-to-understand guidelines to conduct research. It also aims to serve as a quick reference for lecturers, supervisors or mentors who are mentoring scholars from various health science disciplines. It provides a comprehensible overview of the total research process and the various research approaches.

The content in *Research in Health Sciences (2nd edition)* includes ethics in research; how to initiate, formulate and conceptualise research; quantitative and qualitative research approaches; an introduction to epidemiology; consensus-seeking designs, i.e., the nominal group technique and the Delphi technique, as well as other types of research design, i.e., participatory action research and mixed-method research design. The book further guides researchers on how to write a research proposal, report writing and the dissemination of results. Additionally, the book offers guidelines on how to conduct a literature review as well as approaches to conducting research during a pandemic, using COVID-19 as a scenario.

By reading *Research in Health Sciences (2nd edition)*, we hope readers will gain a solid foundation of the concepts of research design and methods and



related research topics, which are presented in a simple and straightforward manner. We trust readers will be able to use the book meaningfully in their academic and professional endeavours.

The Authors  
June 2022

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## About the authors

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**Fhumulani M Mulaudzi** is the South African Research Chair (SARChI) in Ubuntu Community Model in Nursing. She is a Professor of Nursing at the University of Pretoria with 37 years professional experience. She has an National Research Foundation (NRF) rating C3. Prior to her appointment as SARChI, Prof. Mulaudzi was the Head of the Department of Nursing Science for 10 years. She is currently the Deputy President of DENOSA and African Regional coordinator of SIGMA Theta Tau. She has served in many leadership positions. She was the chairperson of the Forum for University Nursing Deans in South Africa (FUNDISA), QUAD member of the African Regulatory Committee and the treasurer of the South African Health Science Deans in South Africa. She is a founder member of the Academy of Science Nursing in South Africa (ANSA). She served as a member of the Council for Scientific and Industrial Research (CSIR) Research Committee for three terms. She also served as a deputy chair for the Bamboo Bridge International which is an organisation promoting traditional healing and other methods of care. Prof. Mulaudzi was a runner-up for the Distinguished Women in Science award 2011 for her work in indigenous knowledge systems research. She is currently the Editor-in-Chief of *Curationis* nursing journal. Her research interest lies in human rights and ethics, HIV/AIDS, indigenous knowledge systems and reproductive health. She is known for promoting the philosophy of ubuntu in nursing ethics. Prof Mulaudzi's work is recognised by her peers, both nationally and internationally. This is evidenced by the number of times she has read papers as a keynote speaker, both in South Africa and abroad.

**Lufuno Makhado** is an Associate Professor in the Department of Public Health, Faculty of Health Sciences, University of Venda. He is the Project Leader of the GladAfrica Epilepsy Research project and the primary South African investigator in Study VIII, The Impact of the COVID-19 Pandemic on People with HIV (multi-country site study). He became a National Research Foundation rated researcher in 2021. He is a member of the Association of Nurses in AIDS Care (ANAC) and the International Nursing Network for HIV/AIDS Research. He is an expert in epidemiology and biostatistics, as well as quantitative research.

**Minrie Greeff** has since 2020 been responsible for developing an integrated research integrity management system for the Faculty of Health Sciences at the North-West University and acts as the Research Integrity Officer of this

faculty. She was the former Head of the Faculty of Health Sciences Ethics Office at the same university (2014–2019) and Professor in Research in the Africa Unit for Trans-disciplinary Health Research. She was project leader of two National Research Foundation (NRF) grants on HIV and AIDS, an NRF Blue Skies research project; the primary South African investigator in a five-year NIH- (United States) funded project; project leader of a SANPAD-funded transdisciplinary project; and an active member in a multinational longitudinal study (PURE). In 2008 she became an NRF-rated researcher and was again successfully rated in 2015. The World Health Organization invited her in June 2009 to serve on a team of experts that formulated guidelines for the disclosure of children's HIV status. Prof. Greeff has received numerous awards, amongst others induction into the Researcher's Hall of Fame of the Forum of University Deans in South Africa (2011); and the most prestigious induction into the International Nurse Researcher Hall of Fame of Sigma Theta Tau International, in Australia on 2 August 2012. She is an inducted member of the South African Academy of Science and Arts and Academy of Science of South Africa (ASSAf). In 2014 she received the Stals Prize for Nursing from the SA Academy of Science. She qualified as a research ethicist in 2014 and was appointed as a member of the National Health Research Ethics Council in 2017 and again in 2020.

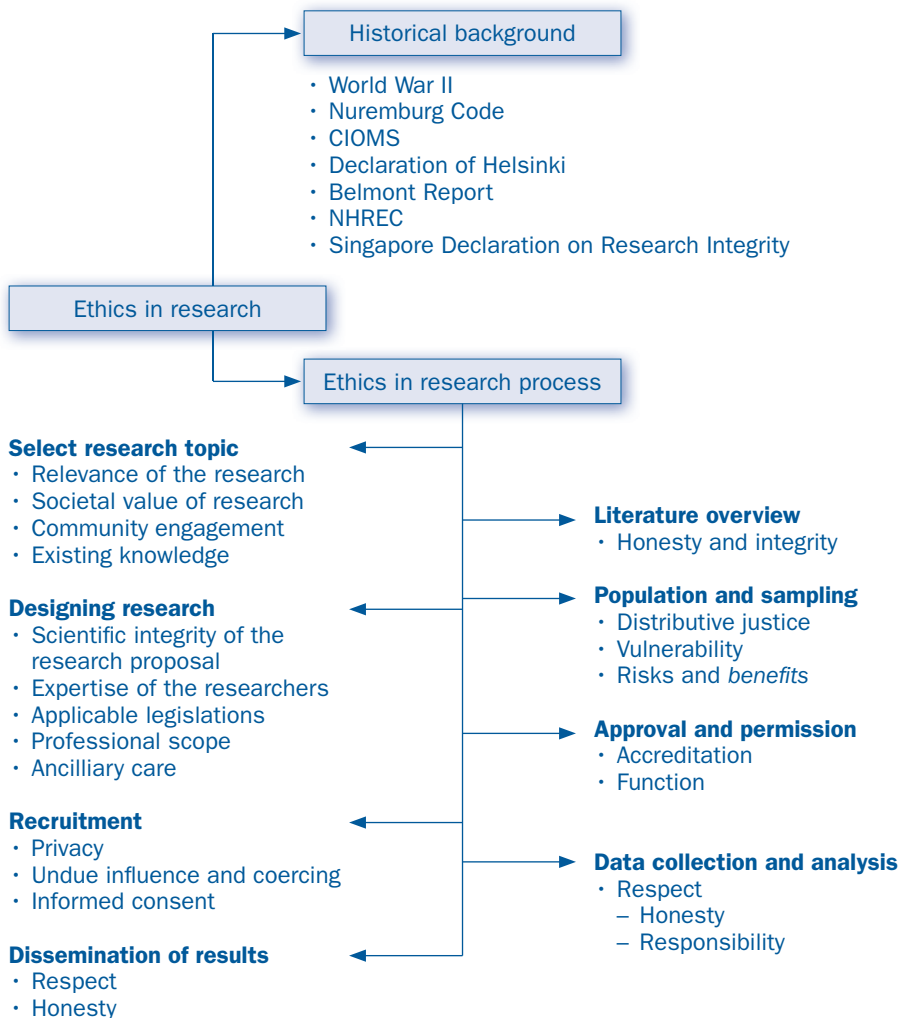
**Yvonne Botma** is a Professor at the School of Nursing, Faculty of Health Sciences, University of the Free State. Her primary role is supervising postgraduate students. She established transfer of learning as a research niche at the School of Nursing. Immersive simulation, including extended realities, falls within this particular niche. Various research teams, using innovative research approaches, explore the complexity of transfer of learning related to nursing education in higher education. Prof. Botma is a National Research Foundation C2 rated researcher, and her research outputs place her within the top five researchers in the Faculty of Health Sciences.



# Chapter 1

## Ethics in research

Yvonne Botma



## Introduction

Ethics and moral decision-making are an integral part of our daily lives, but novice researchers find it difficult to envisage ethics as an elementary part of research. They should understand that academic integrity is part of ethics comprising fundamental values, such as honesty, trust, fairness, respect and responsibility. However, fundamental to these five values is the courage to act on them, even in the face of adversity (Fishman, 2012). These values as well as ethical norms should be integrated into research from conceptualisation since research frequently involves other human beings. The research triad comprises the researchers, participants and the community where the results of the research will be applied. All triad members should be considered and participate during the planning and execution of each research phase. However, all triad members are not equally important during every phase and, in some phases, may not play a role at all.

This chapter aims to demonstrate the application of fundamental values in making ethical decisions during each phase of research. These phases include the following:

- identifying the research topic
- reviewing the literature
- designing the research
- identifying the population
- obtaining permission
- recruitment
- sampling and informed consent
- implementing the intervention and collection of data
- analysing the data
- dissemination of results.

A brief discussion of why ethical guidelines and codes have been developed for research with humans will assist researchers in understanding the imperative of ethical research. Researchers should be familiar with the most recent guidelines of local ethics committees when planning and conducting research. Most health sciences research ethics committees comply with the guidelines of the National Health Research Ethics Committee (NHREC) and the Good Clinical Practice (GCP). The National Health Act No. 61 of 2003 regulates both health and health-related research, involving both humans and animals. The National Health Act No. 61 mandated the development of national guidelines by the NHREC.



## Historical background of codes and guidelines

During World War II, physicians in the Third Reich in Europe committed atrocious experiments on people whom they did not value. These experiments were unethical because the selection criteria for the sampling were racially based, the research participants did not have the opportunity to refuse participation because they were prisoners who were **coerced** to participate, and the interventions led to their deaths or permanent physical, mental and/or social damage. Those involved in conducting the experiments were brought to trial before the Nuremberg Tribunals (USA vs Brandt) that led to the development of the *Nuremberg Code* in 1949 (Nuremberg Military Tribunal, 1949).

### The *Nuremberg Code* contains guidelines for:

- subjects' voluntary consent to participate in research
- the right of subjects to withdraw from studies
- protection of subjects from physical and mental suffering, injury, disability and death during studies
- the balance of benefits and risks in a study.

Despite the *Nuremberg Code*, some **notorious**, unethical studies have been conducted. The Tuskegee study is one of many infamous longitudinal studies where the progression of untreated syphilis was studied in more than 400 African American men. They were examined periodically between 1932 and 1972, but many of them did not know that they were part of the study and that effective treatment (penicillin) was being withheld. They infected their partners, and their children were born with syphilis. Unethical research continues to this day, evidenced by a Google search in mid-2022 that rendered nearly 14 million results of unethical research studies on humans.

Due to the continuation of unethical research, the World Medical Association in 1964 adopted the *Declaration of Helsinki*, which is reviewed regularly. It is imperative that researchers use the latest version of the declaration. The initial *Declaration of Helsinki* differentiated between **therapeutic** and **non-therapeutic** research. However, it was deemed inadequate, and the American government commissioned an investigation to resolve the issue of protecting human subjects in research.

(The *Declaration of Helsinki* can be viewed online at:  
[www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/](http://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/))

The Council for International Organizations of Medical Sciences (CIOMS) comprises diverse member organisations and was jointly established by the World Health Organization (WHO) and United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949. In 2016 a working group published the reviewed *International Ethical Guidelines for Health-related Research Involving Humans*. These 25 guidelines in no small extent underline the guidelines of the NHREC.

The National (USA) Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed in 1978. The commission compiled the *Belmont Report* in which three principles, relevant to research involving human participants, are discussed. These three principles are:

- respect for persons
- beneficence
- justice.

**Respect for persons** requires that the researcher respect a person's **autonomy** and protect those with diminished autonomy. **Beneficence** means not only that the researcher should do no harm, but that the researcher must do good and minimise harm. **Justice** indicates that people should be treated fairly.

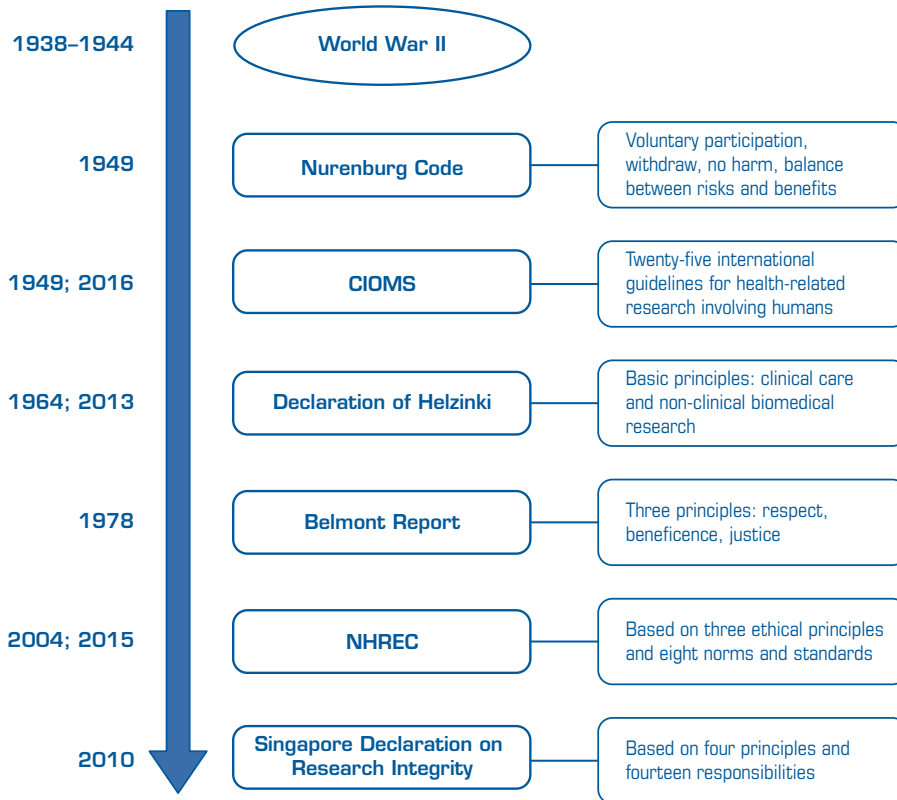
Emanuel et al., (2004) expanded the ethical principles and benchmarks for multinational clinical research to include collaborative partnerships, social value of the research, scientific validity of the research, fair selection of the **study population**, favourable risk-benefit ratio, independent review to enhance public accountability, informed consent from participants, and respect for recruited participants and study communities.

The National Health Act No. 61 of 2003, mandated the NHREC to set norms and standards for research involving humans. To be considered credible, all ethics committees must be accredited by and registered with the NHREC. The NHREC guidelines direct research on humans and animals. A working group reviewed the initial guidelines and published the reviewed guidelines under the title *Ethics in health research: Principles, processes and structures* in 2015. The guidelines embrace the three ethical principles of beneficence and non-maleficence, distributive justice and respect for persons. In addition to these three principles, the guidelines endorse eight norms and standards, namely: relevance and value, scientific integrity, role-player engagement, fair selection of participants, fair balance or risks and benefits, informed consent, ongoing respect for participants, including privacy and **confidentiality**, and researcher competence and expertise (NHREC, 2015).

In 2011, Resnik and Shamoo (2011) published *The Singapore Statement on Research Integrity* that was drafted at the Second World Conference on Research Integrity. The statement comprises four principles, namely: honesty, accountability in the conduct of research, personal courtesy and fairness in

working with others, and good stewardship of research on behalf of others. In addition to the four principles, 14 responsibilities were highlighted.

In addition to the abovementioned codes and guidelines, the researcher should also adhere to locally applicable legislation and GCP guidelines as well as professional ethics codes. Figure 1.1 illustrates a timeline of the various ethical codes and guidelines that have been developed.



**Figure 1.1** Timeline of ethical codes and guidelines

No single set of guidelines is sufficiently comprehensive to address all the issues encountered during research. There is some degree of overlap between the three critical guidelines, and researchers should use all three to inform their behaviour. The guidelines by the NHREC are fairly general while those by CIOMS address various issues – such as remuneration of participants, vulnerable research participants, research in specific situations, and storage and use of data – which are not addressed in the others. The *Singapore Statement* focuses on the behaviour of researchers and addresses issues such as authorship and relations with peers. This chapter describes how these guidelines should be applied throughout the research process.

## Ethics in the research process

Research ethics are not justified by a sentence stating that the principles of ethics have been taken into consideration during the research process. Ethics should be interwoven into every phase and aspect of research – from conceptualisation, planning and implementation, up to writing the report and disseminating the results. The topics that should be considered during each of the research steps are listed in the beginning and then followed by a brief discussion. Integration of ethics in the research process applies to quantitative, qualitative and mixed-method research designs.

### Selecting the research topic

Ethical issues related to the identification of a research topic are:

- the relevance of the research
- the societal value of the research
- community engagement
- existing knowledge

The research topic should be relevant and responsive to the needs of the population or community and should generate valuable information. Societal value cannot be quantified but is determined by the quality of the information, relevance to health problems and the knowledge generated through the research (CIOMS, 2016).

*Clinical research must have social value through the generation of knowledge that can lead to improvement in health. Without social value, research exposes participants to risks for no good reason and wastes resources. (Emanuel et al., 2004, p. 932)*

*The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary nature. (code 2) (Nuremberg Military Tribunal, 1949, p. 182)*

The above quotations clearly illustrate that if research does not have social value, it will harm the community/funders by wasting resources as well as putting participants unnecessarily at risk. Health-related research should be relevant and address the healthcare needs of the population (NHREC, 2015).

According to Dinis-Oliveira (2020), the validity of studies done during an epidemic or pandemic rests on the shoulder of decision-makers such as politicians and researchers. Furthermore, it is also their responsibility to ensure the safety of participants in studies and that the participants rights are preserved.

Research involving humans is rarely, if ever, conducted in isolation. Collaborative partnerships should be considered from the beginning of the research to minimise the possibility of exploitation (social harm) because the community will determine whether the research is acceptable and responsive to their needs. Subsequently, the researcher should identify possible stakeholders or potential partners in the research. Often the role-players consist of the researcher(s), policymakers and the community. If the researcher involves them from the beginning, harmonious values will develop, and the likelihood increases that the research findings will be implemented. Harmonious values will develop when the researchers are honest and demonstrate respect for the community's values, traditions, and social practices and incorporate them into the research design. If the research involves vulnerable groups, for example, those with limited economic development, inadequate protection of human rights and limited understanding of research, it necessitates that the researchers enable the community and policymakers to fulfil their partnership role by building capacity. The true partnership also implies professional courtesy and fairness as well as equitable sharing of financial and other rewards (Emanuel et al., 2004; Resnik & Shamoo, 2011; NHREC, 2015).

Once consensus has been reached on the research that has to be done, the researcher will need to review the relevant literature.

## Literature overview

Ethical considerations during this phase are:

- honesty
- integrity.

In contrast to the collaborative nature of the conceptualising phase, reviewing the literature is a solitary process. Whenever dealing with literature, the researcher has to consider and acknowledge the authors of the used sources. It is unethical to use someone else's ideas or words without acknowledging the source (this is known as plagiarism) and is conflicting with the honesty principle. Honesty requires that opposing viewpoints be stated and that the researcher should not select only those sources that support their stance (Fishman, 2012). Plagiarism is the theft of intellectual property. Therefore, it is unacceptable and may carry heavy penalties once discovered, such as losing all the researcher's academic credits. It has never been easier to **plagiarise** since the researcher can copy material from the internet, cut and paste it, and pretend that it is their work. However, it has also become easy to detect plagiarism with available software. Therefore, the researcher must always acknowledge when using someone's idea, words or style by citing their names, the source where

the idea or words were found and the page number. The researcher may also put the phrase quoted in quotation marks, without rephrasing the wording. The source should be cited in the text as well as in the bibliography. The in-text style differs from that used in the bibliography.

Find out which referencing system the academic institution uses and become acquainted with it. Acknowledge sources consistently and correctly from day one. The internet and other electronic sources require the same acknowledgement but differ slightly from those of a book and an article in a journal. Correct referencing can become quite complex. Use a source that can guide the referencing style prescribed by the academic institution. Follow the instructions meticulously by paying attention to the punctuation and sequence of information. Having read the relevant literature, the researcher now proceeds to designing the research.

## Designing the research

Consider the following when designing the research:

- the scientific integrity of the research proposal
- the expertise of the researcher(s)
- applicable legislation
- professional scope
- ancillary care
- research fatigue.

The *Singapore Statement* (2011) declares that researchers should take responsibility for the validity and trustworthiness of their research. Therefore, research integrity is an ethical requirement (Resnik & Shamoo, 2011; NHREC, 2015) because poorly designed research may deliver unreliable and invalid results. To design valid research means that the researcher must be knowledgeable about research methodologies and adhere to the standards of the selected design. The research design should enhance the social value of the research and realise the aim and objectives of the research. Studies should be scientifically sound, be based on adequate prior knowledge, hence the importance of a thorough literature overview. Furthermore, the research should generate valuable information (CIOMS, 2016).

Researchers should be well qualified to design scientifically sound research as evidenced by their academic qualifications, credentials and previous publications (NHREC, 2015). Furthermore, they must be competent in conducting the research and fieldworkers must be thoroughly trained. The interviewer in qualitative research is the research instrument and should be well trained in the method of data collection. Data collection methods should fall within the scope of the researcher, and the research activities should be within the legislative boundaries of the country.



The health needs related to the research should be anticipated, and treatment options must be made available for participants (CIOMS, 2016). For example, a counsellor should be available if the interview topic is about traumatic events that may evoke strong distressful emotions in the participant. Another example is that there should be a clear standard operating procedure when a researcher discovers abuse of a child while interacting with the participant. Many similar examples exist, and the researcher should state very clearly how participant confidentiality will be maintained or not maintained when it clashes with legislation.

Research ethics committee members may not be able to evaluate the rigour of the research due to the various and explosive expansion of research techniques. Therefore, research proposals should be evaluated by methodological and content experts before submission to an accredited research ethics committee (NHREC, 2015). It is especially important in qualitative research because the theoretical paradigm must be aligned with the aims, data collection methods, data analysis and data interpretation (NHREC, 2015). It is impossible to justify any risk of harm when the research lacks scientific rigour.

Research by students is limited in scope but not depth. Therefore, the same standards regarding methodological integrity apply to all researchers. Academic assessment criteria will be applied in assessing research done by students as they must demonstrate that they can conduct research independently. The safety and wellbeing of participants is primarily the concern of the principal investigator (PI) or research leader (supervisor) (NHREC, 2015).

Researchers should consider how many times potential participants have been asked to participate in research because research fatigue can lead to a refusal to participate in further research (Patel et al., 2020). An example of when research fatigue could occur is if a number of uncoordinated researchers invited the same group of nurses to share their experiences of epidemics or pandemics such as COVID-19.

## Population

Ethical considerations that apply to the selection of the population are:

- distributive justice
- vulnerability
- risks and benefits.

### Distributive justice

The aim and objectives of the research already indicate the study population, which must be appropriate for the research question. In order to meet the ethics criterion of valid research, the researcher should provide a clear rationale for the sample size, sampling method, inclusion and exclusion criteria (NHREC,

2015). The inclusion and exclusion criteria relate to the principle of justice and fairness of selection. Therefore the rationale for each should be reasonable.

The principle of distributive justice requires, on the one hand, that a specific group should not be 'over-researched' and, on the other hand, that others should not be deprived of the opportunity to participate in research. Hence the trend to involve vulnerable people in research when the researcher has specific protection in place to protect their rights and welfare. Under-representation of particular groups like children and adolescents, women, and pregnant and breastfeeding women may perpetuate health disparities (CIOMS, 2016).

### Vulnerability

Vulnerability is nested in respect and autonomy. Persons are vulnerable when their capacity to consent is compromised. Hence, they are susceptible to harm because they cannot protect their interest (Bracken-Roche et al., 2017). Vulnerability is contextual and variable. Therefore, individual and situational factors should be evaluated to determine if a person is vulnerable at that specific time in that specific context. Bracken-Roche et al. (2017) hold the opinion that vulnerability is a relational feature that arises because of a power imbalance between participants and researchers.

Contextual or situational vulnerability refers to personal circumstances, such as mental or intellectual impairment, acute illness, being very young or very old, pregnancy, and childbirth. Environmental circumstances that increase vulnerability are poor socioeconomic conditions, low literacy levels or being unable to access healthcare (NHREC, 2015).

Many authors critique the labelling of vulnerable groups because it leads to exclusion or over-inclusion. Typical vulnerable groups include those who are (CIOMS, 2016):

- cognitively or sensorially impaired
- in hierarchical relationships
- institutionalised
- women, including pregnant women
- politically powerless
- unable to access care
- displaying comorbidities.

Contrary to earlier opinion, children and adolescents should be included in health-related research unless a good reason justifies their exclusion (CIOMS, 2016). Children are vulnerable to coercion or **undue influence** because they have limited freedom or capacity to consent which is dependent on the circumstances and their developmental stage (Gehlert & Mozersky, 2018). A child's capacity to consent can be determined by use of the modified

MacArthur Competence Assessment Tool for Clinical Research (Hein et al., 2015). However, Hein et al. (2015) recommend a dual consent system for children older than 12 years until they have reached maturity. Case-by-case assessment should be done for children between 10 and 12 years and those who are mentally compromised. The parent should permit a child younger than 10 years, and the child should assent. However, the ethics review board should ensure that (Ho, 2017):

- the research might not equally well be carried out with adults
- it is about the health needs of children
- the legal guardian/parent of each child has given permission
- each child has agreed
- each child's refusal is respected.

Randall et al. (2015) are of the opinion that institutions should have standard operating procedures when researchers uncover child abuse in order to safeguard both researchers and the population being studied.

Convenient selection of poor or marginalised individuals or groups expose them to coercion and exploitation because they may not have access to care unless they participate in the research, or they may have a dependent status and may be easy to manipulate (Gehlert & Mozersky, 2018). Furthermore, these already marginalised groups may not be able to access the benefits of the research. Groups that are easily 'over-researched' are students in researchers' classes, residents of long-term care facilities, subordinate members of hierarchical organisations, and communities with limited access to healthcare (CIOMS, 2016).

COVID-19 has highlighted the increased risk of people with comorbidities developing severe disease. The comorbidities in an epidemic or pandemic may differ, but should be considered to reduce the risk of those with specific comorbidities. It is the responsibility of the researcher to abide by the safety precautions as declared by the government.

A goal of health-related research should be to enable individuals and groups to become less vulnerable. It is no longer sufficient to focus on **voluntariness** and harm reduction or prevention (Ho, 2017). Therefore, it must be clear how the community that will bear the risks associated with the research will benefit from it. If the participants will not benefit directly, research must, at the very least, clearly articulate how they will benefit in the near future, or how the group they represent will benefit from the research.

## Benefits

Anticipated benefits should outweigh the potential harms (NHREC 2015). Benefits are classified as direct or societal benefits. Participants may benefit

directly from participating in the research when they receive treatment for the medical condition during the study (at no cost), develop a better understanding of their condition, receive healthcare services, such as a physical examination or laboratory tests, and experience satisfaction of performing an altruistic act (Mazur & Goldfarb, 2015).

Societal benefit or social value should be considered if participants do not benefit directly. The social value of research is the benefit that the intervention will bring to future patients or society (Habets et al., 2014). Societal benefits comprise the availability of the treatment in future, generalisability of knowledge and possible reduction in the cost of providing medical care (Mazur & Goldfarb, 2015).

Remuneration of research participants is not considered a benefit because it is a recruitment strategy or reimbursement for actual expenditure, time, effort and inconvenience (Largent & Lynch, 2017).

Others who benefit from research are the researchers and the organisations for whom they work. Institutions benefit from an increase in their research capacity. Researchers may benefit by being recognised as valued researchers in their field of work. Economic benefits may accrue to researchers and the institutions for whom they work. For example, academic institutions receive a state subsidy for research published in accredited journals (National Bioethics Advisory Commission, 2001).

## Risks

Risk equates to harm or injury and implies that something detrimental could occur in the future. The researcher should consider the likelihood that harm may occur and the magnitude or significance of the harm (CIOMS, 2016). Seven types of harm can occur, namely: physical, psychological, social, economic, legal, dignitary and reputational.

**Physical harm** usually consists of fatigue, headaches, boredom, discomfort and muscle tension and relates to the types of intervention and data-collection techniques. If the intervention is the administration of a new drug, the physical harm may be side-effects of the administered drug. Testing a new drug implies that blood samples must be taken and therefore the discomfort and possible bruises associated with vena puncture may be expected (Grove et al., 2013).

During an epidemic or pandemic, the researcher may cause physical harm by exposing the participant, and therefore the community, to the contaminants or organism, thus spreading the disease. Contamination could work a number of ways: the researcher may become infected when in contact with an asymptomatic participant; the researcher may be asymptomatic and infect a participant or asymptomatic participants (in a context of multiple participants) could infect one another. Therefore, the researcher should adhere

to all the precautionary measures and oversee that participants have all the necessary equipment and that they too adhere to the precautionary measures (Meagher et al., 2020).

**Psychological or emotional harm** may be due to self-disclosure or introspection or answering personal questions that cause embarrassment. It usually manifests as anxiety, fear, anger or sadness. Experiencing those emotions up to a certain degree is acceptable, but the researcher should be sensitive to notice when they are too intense and refer the participant to appropriate support or treatment facilities (Polit & Beck, 2017). Unusual levels of temporary discomfort may be experienced during the study and after the termination of the study, for example, if participants are asked to describe their hijacking experience. Reliving the experience may elicit extreme fear or anger that may linger on after the interview has been conducted (Grove et al., 2013).

**Social harm** involves the negative effects of the researcher's interactions or relationships with others and is realised in stigmatisation or employment discrimination (Grove et al., 2013). For example, a study aimed to determine whether peer support for HIV-positive patients influenced adherence. Social harm was caused in those who did not disclose their HIV-positive status to their neighbours. Because the peer supporter visited the participant twice a week, the neighbours started asking questions, and they found out that it was an HIV study. Therefore, they concluded that the person being visited by the peer supporter was HIV positive. It was also an unintentional violation of privacy because the HIV status of that person was disclosed to the community without his permission. This type of risk should be explained to the participant in the information leaflet.

Alternative data collection methods, for example, electronic and social media platforms, may not be secure for data storage. Additionally, living in crowded spaces may also incur social harm when electronic methods are used for data collection. Technical assistance may be needed to ensure confidentiality and to prevent possible social harm (Sevelius et al., 2020).

**Economic harm** involves the imposition of direct or indirect financial costs on the participants, such as costs incurred for travelling to the research site, paying for childcare, financial loss because they have to take time off from work, and the cost of the time they spend at the research site (Grove et al., 2013). The researcher may not expect participants to incur expenses to take part in research. Consult the research ethics committee's guidelines on remuneration of participants. Most ethics committees require that the researcher submit a planned payment schedule and amounts with justifications. When a research participant is accompanied by a carer or a parent or a guardian, both should receive the remuneration (NHREC, 2015).

**Legal harm** occurs due to actions taken against the participant, for example, arrest, conviction, incarceration or lawsuits as in cases where the researcher is legally bound to report specific actions such as child abuse (National Bioethics Advisory Commission, 2001).

**Adventitious harm** may result from incorrect or poor implementation of public health policies or harmful individual behaviour during epidemics or pandemics (Erren et al., 2020). Researchers encounter an ethical dilemma when they observe people not adhering to precautionary measures, for example, not adhering to personal distance restrictions or not wearing their masks during a pandemic. Should these infractions be reported to authorities or not?

**Dignitary harm** is 'incurred when individuals are not treated as persons of value, preferences or commitments, but rather as mere means, not deserving of respect' (National Bioethics Advisory Commission, 2001). Dignitary harm occurs when respect is not valued.

**Reputational harm** may occur if researchers from an institution cause participants to become ill and society makes the association that the institution contributed to the spread of the disease (Tindana et al., 2020).

Risks may be posed by design features, such as randomisation, placebo studies, methods such as sensitive interviewing or questionnaires, and interventions such as organ biopsies and venipuncture.

There are four dimensions to risk that should be described, namely: nature, magnitude, probability and expected duration. Minimal risk is equitable with the probability and magnitude of harms encountered during routine physical or psychological examinations or tests (CIOMS, 2016). The minimal increase above minimal risks comprises a fraction above the minimal risk threshold and should be considered acceptable by a reasonable person (CIOMS, 2016). Dissemination of results about epidemiology and genetics may put communities, societies, families or racially defined groups at risk. Researchers working with, for example, radiation or virulent microorganisms, may be at risk (CIOMS, 2016).

Studies that involve reviewing documents have no predictable effect because the researcher does not interact directly with the 'participant'. However, to prevent the violation of privacy, all information should be depersonalised.

### Minimisation of risks

Examples of strategies that may reduce risks (CIOMS, 2016; The National Bioethics Advisory Commission, 2001) include the following:

- a valid study design
- competent and well-qualified researchers and fieldworkers
- the necessary infrastructure to deal with any adverse event and harmful **sequelae**



- privacy and confidentiality of participants are adequately protected
- participants are monitored for harmful effects
- a timely treatment plan is in place in case of harm
- prospective participants at undue risk of harm are excluded from the study
- institute clear criteria for terminating a study
- seek exemption to report illegal activities, for example, where prostitution is against the law
- limit invasive procedures
- adhere to preventative measures during epidemics and pandemics, for example, maintain personal distance, practise good hand hygiene, and wear a mask.

### **Risk-benefit ratio**

Calculating the risk-benefit ratio is a subjective exercise because no quantitative measures or values can be accrued to every single risk or potential benefit. The ratio is determined on the maximised potential benefits and the minimised risks. The potential benefits should always outweigh the risks. If the risks cannot be further minimised, the researcher should justify them. Consider another study or revise the study design if the risks outweigh the benefits. It is the responsibility of the researcher to outline the benefits and risks and to calculate the ratio. It must be part of the proposal that the researcher submits to the ethics committee. Three different groups of people, namely the researchers, the ethics committee, and the potential participant will interpret the calculated ratio. Figure 1.2 depicts the process to determine the risk-benefit ratio.

### **Approval and permission**

The research ethics committee should adhere to the criteria of:

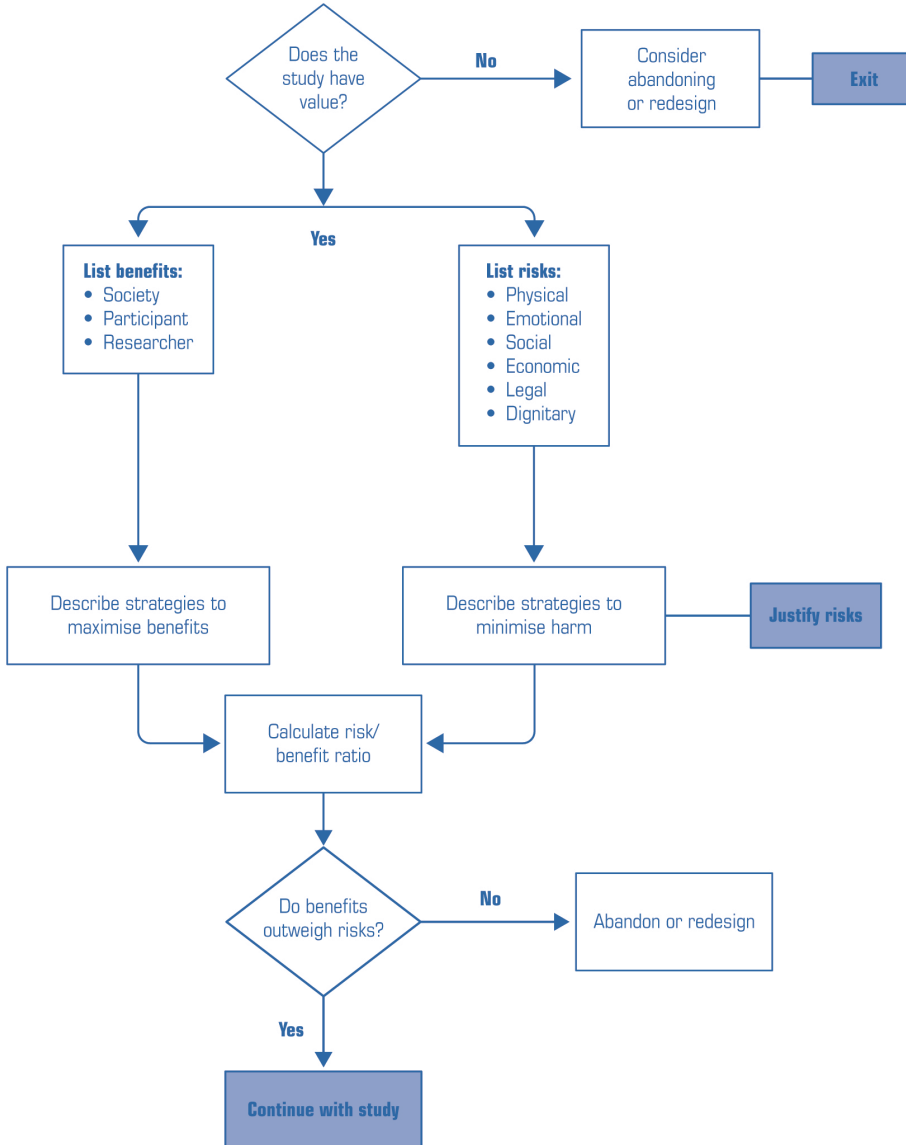
- accreditation
- function.

### **Accreditation**

Research that uses data that are available in the public domain, involves observation of people in public spaces and natural environments, exclusively rely on secondary use of anonymous information, or anonymous human biological materials, and quality assurance or improvement studies, programme evaluation activities and performance reviews need not undergo formal ethics review (NHREC, 2015). However, it does not mean that ethical considerations are irrelevant to the study.

An accredited research ethics committee must review all research involving humans in South Africa (NHREC, 2015). When appropriate, the South

African drugs regulatory authority – the Medicines Control Council (MCC) – should also review the research. Research may not commence unless the researcher has received notification of approval.



**Figure 1.2** Process to determine risk-benefit ratio

## Function

The primary function of an ethics committee is to protect both the researcher and participant. It fulfils this function by reviewing the research proposal for sound scientific methodology, validity, and social value. The Research Ethics Committee usually scrutinises the informed consent process. The ethics committee also has a monitoring function, and it may stop research when there is misconduct by the researcher or when harm exceeds the benefits. The *Singapore Statement* explicitly mentions that it is the responsibility of a person to report irresponsible research practices and to respond appropriately to allegations of irresponsible research practices (Resnik & Shamoo, 2011).

Furthermore, ethics committees must hold researchers accountable for the research activities. Permission to conduct research must be obtained from the relevant institutions before recruiting and screening of potential participants may commence. For example, a university official (such as the rector) must provide permission if the population consists of students, while the Department of Health must do the same if the researcher wants to research their facilities (staff as well as patients).

It may not be the rector at the researcher's university; but the principle is universal.

The extent of the research determines whether permission must be obtained at district, provincial or national level. The chief executive officer of the specific institution, as well as the head of the department where the research will be conducted, should give permission. All stakeholders must grant permission in writing. Obtaining permission from all the relevant parties is often a laborious process that can take a long time. The highest authoritative person grants the first permission per institution. Recruitment and sampling may only commence after ethics approval and permission has been granted from the various stakeholders.

These principles remain standing during extraordinary circumstances, such as epidemics and pandemics. However, Erren et al. (2020) are of the opinion that data collection may commence in a 'natural' experiment while the researchers are seeking ethics approval. A pandemic, such as COVID-19 where extreme lockdown measures were implemented, may necessitate changes to the original research proposal. All changes to the research proposal should be approved by the ethics committee before execution (Flemming et al., 2020). Any changes to the study should not jeopardise the integrity of the study nor the protection of the participants (Setiabudy, 2020).

Obtaining ethics approval and permission from the various institutions may co-occur. Provisional approval may be granted on the premise that the researcher has obtained approval/permission from the other organisation.

## Sampling (Recruitment and informed consent)

Ethical considerations during recruitment and enrolment include, but are not limited to, the following aspects:

- privacy
- recruitment (undue influence and coercion)
- informed consent.

### Privacy

Before the researcher can enrol participants into the study, the researcher needs to access the target population. The community or relevant stakeholders may pave the way for accessing the target population. The right to privacy – which includes autonomy over personal information – is a common-law and constitutional right and may be important during the recruiting phase. It means that clinicians must ensure that information concerning their patients remains confidential. This principle should be taken into consideration if the target population can only be reached via another practitioner.

An example is if the researcher wants to research HIV/AIDS patients in private practice. The practitioners of that practice are not allowed to give the researcher any contact details or information about their patients. If they do give the researcher information which will enable them to contact potential participants, that clinician will be liable for breach of confidentiality. However, the practitioner can ask permission from the patient to share his or her personal information with the researcher.

The right to privacy is also important when using clinical records in research. Research that involves access to personal health records must receive approval from a research ethics committee. **Retrospective** record analysis may be done without patient consent, provided it is done **anonymously**. **Prospective** record analysis requires patient consent. No unauthorised persons may have access to the information, and the investigators involved must sign a confidentiality agreement. Information derived from personal clinical records stored on computers requires the same safeguards as paper-based records.

### Recruitment

Coercion and undue influence are threats to voluntary participation during the recruitment phase of the research project. Coercion occurs when the researcher threatens to harm the potential participant should he or she decide not to participate. Undue influence is when the researcher offers the potential participant an excessive, unwarranted reward to obtain compliance (Largent & Lynch, 2017).

The recruitment plan should reflect the local protocols of the ethics committees and meet the local and national requirements. Meeting local

requirements implies that recruitment methods, as well as measurements, are culturally sensitive (Halkoaho et al., 2016). Sometimes researchers use payment for participation in the research as a recruitment strategy. Paying or reimbursing research participants may be interpreted as an undue influence as persons may take unwarranted health risks to participate in studies that pay them well (Tseng & Angelos 2017). People that enter studies for payment may provide false information to stay in the study, hide contraindications, or incur self-harm to earn the stipend. However, it is often necessary to use incentives to ensure that people will enrol and remain in high risks studies (Brown et al., 2018). Incentives take on many forms, such as money, gifts and services.

On the one hand, incentives may be construed as an undue influence when the study population is vulnerable. On the other hand, it is unethical not to reimburse participants for their expenses, time and inconvenience. Therefore, participants may be remunerated for their time, inconvenience and expenses (TIE principle) based on the amount paid for unskilled labour in the marketplace. The family member that accompanies a child should also receive the stipend (NHREC, 2015). The proposal must contain the remuneration schedule with the justification of the schedule as well as the amounts.

Power coercion is a high risk in education research or where potential participants are in a subservient position to the researcher. Widely used forms of control are coercion, intentional deception, manipulation and inappropriate disclosure (Bromwich & Rid, 2015).

Researchers should recognise the individuality of each potential participant by considering the level of education when they provide information about the research. Furthermore, researchers should consider that individualistic decision-making may not be the norm in some communities. Therefore, they should respect the family relationships and societal status of the potential research participant (Halkoaho et al., 2016) by allowing them time to discuss their participation in the research with their significant others. Criteria similar to obtaining informed consent apply to recruitment and include the following (Halkoaho et al., 2016):

- the language used must be accessible
- the research process must be clear
- participation must be voluntary
- access to care without participation in the research must be available
- there must be direct or indirect benefit of participation.

### **Informed consent**

Autonomy or self-determination is the underpinning principle of informed consent (Bromwich & Rid, 2015). The associated values are respect and honesty. Obtaining informed consent is not a quick signature on a document; it is a process that starts during recruitment, although procedures and results may

necessitate obtaining consent during the study (Petrova et al., 2016). Informed consent is an iterative conversational process with due consideration of the complexity of the context (Dove et al., 2017) and comprises four elements, namely disclosure, comprehension, voluntariness, and documentation.

Each ethics committee has specific criteria that should be included in the information leaflet. The generic information required is listed below:

- nature and purpose of the research
- beneficiaries and benefits of the study
- an explanation of the way that data will be collected
- the duration of the study
- selection criteria for the study and how the participant was selected
- responsibilities of the participant and the researcher
- the risks or discomfort involved in participating (physical, psychological, emotional, economic or social)
- remuneration of participation, if any, and how much and when
- voluntary participation with no retribution on refusal
- withdrawal at any time during the study with no retribution
- confidentiality and steps taken to maintain it
- any possibilities of disclosure by participants and what will be done about this
- length of time participants have to decide if they want to participate or not
- how data will be protected and stored, and for how long
- how the study is being funded/who is sponsoring the study
- dissemination of research findings
- credentials of the researcher(s)
- contact details of the researcher(s) for inquiries
- contact details of the ethics committee should participants want to lodge a complaint.

Additional information is required for clinical trials, namely:

- information about the research related health condition
- the intervention or proposed treatment
- any experimental procedures including randomisation and blinding
- alternatives to the research options if it is therapeutic research
- nature of the disease and possible outcome if left untreated
- explanation of how side-effects will be managed and who will be responsible for any associated expenses
- handling of comorbidities
- insurance coverage in case of injury
- disclosure if the intervention/drug will be available on completion of the trial.



Power dynamics and gender inequalities are threats to voluntary consent (Bromwich & Rid, 2015; Thakkar et al., 2018). Informed consent is an ongoing dialogue during which the researcher shares information regarding the study and answers questions or addresses participants' concerns. Amendment of the research protocol due to extraordinary circumstances such as COVID-19 implies that participants should be informed about the changes and reaffirm their consent. It is imperative that the researcher ensures that the participant understands the fundamental purpose of the study and study procedures (McCormack et al., 2018; Purcaru et al., 2014; Thakkar et al., 2018). There are numerous reasons potential participants might not understand these, including the following:

- language barriers
- age (too young or perhaps too elderly)
- psychiatric illnesses
- poor decision-making capacity
- inability to fully understand the information or an inability to express their choice (Thakkar et al., 2018)
- educational level
- critical illness
- study phase and location (Tam et al., 2015).

Researchers can overcome barriers to comprehension by using simple language in the mother tongue of the participant and providing sufficient time to discuss the invitation to participate in research with significant others. Various readability software programs are available (e.g. the SMOG Index, the Gunning Fox Index, amongst others) to determine at which level the information is pitched. For an average adult, it should be written at about seventh or eighth grade, reading level 7–8. The tone should be invitational and not overly persuasive. Concepts should be used consistently, and no jargon or technical terms may be used. The coherent, logical organisation of the content in a culturally appropriate format is essential. The font size should not be smaller than 12 points for the older population (Polit & Beck, 2017). Frequencies rather than percentages should be used (Bromwich & Rid, 2015).

The researcher may assume understanding in low-risk studies but should informally verify understanding. However, formal verification of comprehension should be done in moderate- to high-risk studies (Bromwich & Rid, 2015).

It is compulsory to document the informed consent process as well as the topics that were discussed. The informed consent process can be audio-visually recorded or signed, or a thumbprint may be obtained (McCormack, et al., 2018). During extraordinary circumstances, such as epidemics or pandemics, an independent person should obtain informed consent and be

physically present. Four parties must sign the consent documents at the same time with the pairs being in different locations. After signing, the participant should send the signed document electronically to the researcher. The participant may take a photograph of the signed document and send it to the researcher via WhatsApp, who has to save it in a file. The strategy described is to compensate for the absence of an independent person in obtaining informed consent. The researcher and the participant both keep a copy of the signed informed consent letter.

Consent is implied when a respondent (participant) sends the completed questionnaire back to the researcher. However, it must be clearly stated on the questionnaire, as well as in the accompanying letter, that by completion of the questionnaire, consent is given to partake in the research. The information sheet that accompanies the questionnaire should outline all the information as discussed previously.

## Data collection and data analysis

The values underpinning data collection phase are:

- respect
- honesty
- responsibility.

### Respect

Respect for people is demonstrated by maintaining **anonymity** and confidentiality. Anonymity means that even the researcher does not know to whom responses belong, for example, questionnaires with no identifiable data were posted and returned. Anonymity cannot be achieved in qualitative studies because qualitative data collection involves face-to-face techniques, such as focus group interviews, in-depth interviews and nominal-group interviews.

Confidentiality pertains to how the researcher manages personal information to ensure that only the researchers directly involved in the study have access to the information and that information is not willingly or unintentionally shared with other people unless the participant has consented to share the information. Data collected via social media and other electronic platforms such as Zoom, Google Meet, Microsoft Teams and Skype may not be secure. Therefore, the researcher should download and store the data securely as soon as possible after having collected it and then delete the data from the electronic platform. A break in confidentiality may be necessary when the researcher becomes aware of the transgression of the law by a participant (Petrova et al., 2016). Sometimes participants feel strongly about their story and may insist that their name is mentioned and that they are recognised for their contribution to the research.

Safeguarding measures, such as password protection for electronic data and keeping hard copies under lock and key limit access to data (Petrova et al., 2016). Information may be exposed to a typist who transcribes the taped recordings. Although participants of a focus group interview are requested to keep the information confidential, this cannot be guaranteed. To enhance the credibility of the research, an independent auditor is often asked to assess the audit trail which includes the initial recordings and transcriptions. A co-coder is also often asked to assist with the data analysis to enhance trustworthiness. Co-researchers should sign a confidentiality clause.

When absolute confidentiality cannot be maintained, the participants should be informed; they should also know who will have access to the data before committing themselves to participation. The value of confidentiality differs across societies. Some societies may think that there is a conspiracy if interviews are conducted in private. The researcher should be sensitive to such issues and, if necessary, adapt the data-collection process to respect the culture of the society. Nonetheless, the norm is for researchers to do everything in their power to ensure confidentiality (Grove et al., 2013).

Maintaining confidentiality becomes challenging when conducting studies in an environment where the researcher and the participants know each other. It is easy to let some information slip during a conversation, or people may ask the researcher to see what another person said. It is a breach of confidentiality when information is willingly or even unintentionally shared with an unauthorised person.

## Honesty

The participants in qualitative studies have to trust the researcher; therefore the researcher has to create a reciprocal and honest relationship with the participants (Petrova et al., 2016). Honest researchers will not plagiarise, **fabricate** or falsify information. Nor will they selectively delete data, or modify data after performing initial data analysis (Bouter et al., 2016; Wallach et al., 2018). Prevent fraud by checking data often and openly in front of those who collect and analyse the data. Query any suspicious marks on data sheets, for example, changes or corrections. The right way to correct a mistake on a data sheet is to draw a single line through the incorrect recording and to date and initial it. Write the correct information with an explanation, if necessary, next to it. The original recording must still be readable. This guideline applies to electronic data as well (International Council for Harmonisation (ICH GCP), 2016).

Dishonest behaviour undermines research; it undermines regulatory decision-making regarding drugs and treatments and clinical decision-making when care guidelines are based on low-quality research findings (Wallach et al., 2018). Furthermore, dishonesty in research leads to mistrust and erodes the

academic communities' believe in the value and meaning of scholarly research, teaching and degrees (Francisco et al., 2017).

Honesty is also a way of showing respect. Therefore, the time participants spend on research activities should not exceed the time specified during recruitment and in the information leaflet.

Digital recording, with permission from the participants, allows the researcher to verify their exact words and enhances the trustworthiness of the research (Petrova et al., 2016).

Globally, a cry for sanctions against dishonest researchers is being heard. Institutions are retracting degrees or credits towards degrees of unethical researchers. Funder organisations blacklist dishonest researchers who may then no longer serve on their committees or receive funds from competitive grants. Journals require evidence of ethics approval and clear datasets that will enable them to replicate the analysis (Francisco et al., 2017). Therefore, it is essential for researchers to become familiar with local academic integrity policy and to be honest in all the research steps.

## Responsibility

It is the researcher's responsibility to adhere to the research proposal that was approved by the research ethics committee and the information distributed in the information leaflet. No new interventions, procedures or techniques that have not been described in the information brochure should be executed. If a new intervention, procedure or technique needs to be used, new informed consent must be obtained.

Only a competent researcher or fieldworker may execute a research procedure. It is the responsibility of the principal researcher to ascertain that the fieldworker is skilled and competent.

It is everybody's responsibility to report the misconduct of researchers. Therefore, participants should have contact numbers they can use to make complaints. Appropriate professional assistance, support or treatment at the researcher's expense should be offered to them if they have been harmed in any way.

A researcher is also responsible for the efficient and economical management of resources, whether fiscal, human or material. It is irresponsible therefore, unethical, to squander resources or use grant money for purposes other than specified in the proposal (Emanuel et al., 2004).

## Report writing and dissemination of results

The values pertinent to the phase of reporting and dissemination of results are:

- respect
- honesty.

Respect comprises maintaining confidentiality. Therefore, data should be reported in an aggregate form because nobody should be able to identify an individual from the results published. Long and Johnson (2007) suggest that research sites should not be specified but be referred to in vague terms, such as 'a district hospital in the Free State'. The location should preferably not be smaller than a province.

Inadvertent disclosure, also called deductive disclosure, may occur through in-depth biographical information, detailed description of the context and even direct quotes (Petrova et al., 2016), especially when the target population is a small, high-profile group. Other researchers should be respected. Therefore, give recognition to their ideas or phrases by referencing sources (Bouter et al., 2016).

Withholding methodological details or results lead to a lack of transparency and reproducibility which, in turn, erodes confidence in the entire research enterprise (Wallach et al., 2018). By publishing incorrect or fraudulent results, the author is lying to the public and is violating the value of veracity (truth and truth-telling). This could also influence future research because researchers may use biased publications during their literature reviews and thus base their research on false information. Various strategies are being implemented to encourage researchers to be honest. Many journals expect researchers to share their datasets with the statistical code that underpins the publication. Funders may expect that the research proposal contains a data sharing plan, inclusive of data and the appropriate statistical code (Wallach et al., 2018). Authors must publish both positive and negative results because refuted hypotheses are as valuable as those supported by the results.

Claiming work done by others as one's own could also be perceived as misconduct. Each author must contribute significantly to the conceptualisation or data collection and analysis of the data, and either write or critically read the manuscript, and approve the pre-published version of the manuscript. Authors are accountable for all aspects of the work (International Committee of Medical Journal Editors, 2018).

## Conclusion

Guidelines for ethical research on humans developed because atrocious experiments were conducted on humans during World War II. Despite the Nuremberg guidelines, unethical research continued, and therefore more specific guidelines were developed by various organisations. Some legislation and guidelines govern research. Although the three principles of respect for humans, beneficence and justice remain pertinent in guiding ethical research, values such as honesty, reciprocity, responsibility and integrity have moved to the forefront. These principles and values are interwoven throughout the research process and should be considered from the planning phase to the publication of research findings.

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## Research in practice

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The most important aspect of these learning activities is to demystify whatever perceived schisms you may perceive between theory and practice in nursing and healthcare as disciplines. Furthermore, these learning activities provide an opportunity for the actualisation of the content of this chapter, in order to allocate a significant degree of practicality to what may initially seem impractical or abstract.

### Activity 1.1

Discuss how the expansion of the research ethics guidelines impact on the execution of research.

### Activity 1.2

Explain why vulnerable groups should not be excluded from research.

### Activity 1.3

Explain the different types of harm and mechanisms to decrease these risks.

### Activity 1.4

Distinguish between undue influence and coercion.

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