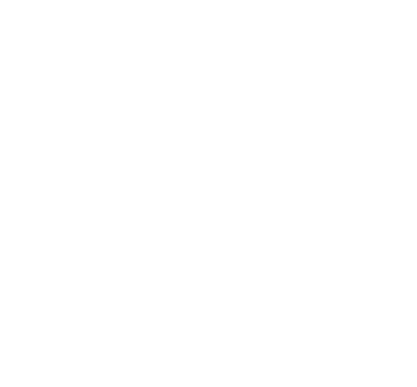
**UNIT 4**

**Ethics in Health Research**

# 1 Introduction



You have by now reached the point where you should have taken some of the first steps in developed a draft research protocol or project, which includes aims, objectives, as well as a discussion of your research design and methodology, and a literature review. In this session, we will review a critical step in preparing any research study, namely, considering its ethical considerations so as to be able seeking research ethics clearance for a study.

As a student of the University of the Western Cape, you need approval from the Faculty of Community and Health Sciences Higher Degrees Committee that your research is sound. In addition to that, you will need ethics clearance to conduct research from the relevant UWC Research and Ethics Committee. In the case of the School of Public Health, this is the UWC Biomedical Ethics and Research Committee (BMREC). Once these committees approve your protocol/proposal, you will also need, where appropriate, to approach relevant institutions in the places where you will conduct your research, for approval or permission.

## Contents

1 Readings

1. Philosophical Principles of Ethical Research
2. Informed consent
3. Points for a Participant Information Sheet
4. Summary
5. Assignment 2 due
6. Conclusion of Unit 4
7. References

## Timing

This unit has with three readings and three tasks. It should take you approximately three hours to complete.

## Learning Outcomes

By the end of this unit, you should be better able to meet the intended learning outcomes in the first column; they are part of or relate to the overall Module Outcome in the second column:

|  |  |
| --- | --- |
| **Unit Outcomes** | **Module Outcomes** |
| * Understand the philosophical principles guiding ethical research in public health. * Understand the principles of informed consent. * Compile a participant information sheet. * Apply ethical considerations to ensure | * Critically assess Health Research Ethics issues and strategies |

# Readings

**Wassenaar, D.R.(2007). Ch 4 – Ethical issues in social science research. In Terre Blanche, M. & Durrheim, K. (Eds). *Research in Practice: Applied Methods for the Social Science:* 67-. Cape Town: UCT Press.**

**Polit, D. E. & Hungler, B. P.(1993). Ch 5 - The Ethical Context of Nursing. In *Essentials of Nursing Research, Methods, Appraisal and Utilization*. Philadelphia: J. B. Lippincott Company: 125-147.**

**Cash, R., Wikler, D.,Saxena, A. & Capron, A.(2009). Chapter 4 – Voluntary Informed Consent. In *Casebook on Ethical Issues in International Health Research*: Geneva: World Health Organization: 83 - 92.**

The full document : Cash *et al.* (2009, is available at the following website:

whqlibdoc.who.int/publications/2009/9789241547727\_eng.pdf

***In addition: Go through Dr Ernesta Kuneke’s powerpoint presentation that is uploaded under Winter school resources*.**

# Philosophical principles of ethical research

Ethics approval is required whenever we conduct health research with human beings. Cash *et al*. (2009:38) distinguish **health research** that requires ethics approval as:

*… any social science, biomedical or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge,*

*in which human beings*

* *are exposed to manipulation, intervention, observation, or other interaction with investigators either directly, or through alteration of their environment, or*
* *become individually identifiable through investigators’ collection, preparation, or use of biological material or medical or other records.*

Thus far this module has been concerned about familiarizing your with the scope of public health, identifying relevant research problems and developing an appropriate study design and approach. Before embarking on the particular methodologies in conducting the research you should be aware of ethical implications related to your proposed research.

**READINGS**

**Wassenaar, D. (2007). Ch 4 - Putting Design into Practice: Writing and Evaluating Research Proposals. In Terre Blanche, M. & Durrheim, K. *Research in Practice: Applied Methods for the Social Sciences.* (Eds). Cape Town: UCT Press: 65 - 71.**

**Polit, D. E. & Hungler, B. P. (1993). Ch 5 - The Ethical Context of Nursing. In *Essentials of Nursing Research, Methods, Appraisal and Utilization*. Philadelphia: J. B. Lippincott Company: 125-147.**

There are four basic ethical principles that are applicable to research which are explained in the readings:

* Autonomy and respect for the dignity or persons
* No maleficence
* Beneficence
* Justice

More than knowing these words, it is essential that you try to express these principles in your own words, to check your understanding thereof.

**TASK 1 – Consider ethical issues in your research**

1. **Consider the relevance of the four ethical principles of research in your study: *autonomy, nonmaleficience, beneficence* and *justice*. Write a paragraph on each in relation to your study.**
2. **How will you keep the identities of your research participants confidential?**

### FEEDBACK

1. You may have found this task difficult, as there are no clear right/wrong answers.

The critical issue with ethics is that you need to *consider* the principles, *argue* their relevance to your proposed research and then *illustrate* compliance through preventive actions. Wassenaar (2007) recommends an ethical framework which outlines a coherent set of benchmarks to evaluate the ethical merits of proposed research:

* + Collaborative partnership
  + Social value
  + Scientific validity
  + Fair selection of participants
  + Favourable risk/benefit ratio
  + Informed consent
  + Ongoing respect for participants and study communities

You may find these useful when preparing an application for ethical clearance.

1. Depending on the nature and type of study, you could assign codes or code names to participants. In certain instances where you extract information from health registers, it is simply a matter of not extracting personal identifying information. In qualitative research, where people from certain designations can be easily identified, you need to consider how their organisation and job title can be masked.

# Informed consent

The first principle in the Nuremberg Code - which provided the groundwork for research ethics - states that “*The voluntary consent of the human subject is absolutely essential”.*

In the Code the three qualities of valid consent are emphasised:

* + The capacity to give consent
  + Acting voluntarily
  + The provision of sufficient and comprehensible information to make an enlightened decision.

**READING**

**Cash, R., Wikler, D., Saxena, A. & Capron, A. (2009). Ch 4 – Voluntary Informed Consent. In *Casebook on Ethical Issues in International Health Research*. Geneva: World Health Organisation: 83 - 92.**

Obtaining informed consent is critical in the research process, because it provides a sense of *assurance of self-determination and autonomy* of and *protection* for the participants as well as a measure of *transfer of responsibility* to the participants.

### TASK 2 – Individual vs collective consent

1. **Consider case 23 on “Testing high doses of vitamin A on children” (Cash *et al*, 2009:92).**
2. **Answer the questions 1 – 6.**

**FEEDBACK**

This is again a case where there are no right/wrong answers. The learning principle is that ethical issues are just that: “issues” - dilemmas that need to be negotiated. Later in this semester you will be invited to the Google group discussion with your fellow colleagues doing this module. I invite you to post your thoughts and let us see whether

we can harness the collective intelligence to find a favourable resolution(s) for this ethical dilemma.

Read again the section on “The functions of consent” on pages 86-87, in Cash *et al.*

(2009), and consider your response.

# Participant information sheet

The Participant Information Sheet is a short document/letter which explains the research and requests consent from the participant.

All Proposals sent to the Higher Degrees Committee and BMREC should be accompanied by a Participant Information Sheet. The Participant Information Sheet needs to be on an official departmental/school/faculty letterhead. Although you will not have to prepare a Participant information sheet at this stage, it is worth knowing the type of information that needs to be in this sheet.

The Participant Information Sheet MUST at a minimum include the following:

1. Clearly explain the nature of the research;
2. Indicate that the research will be used for obtaining a degree;
3. Indicate what other purposes (if any) the research would be used for;
4. Explain any (especially adverse) consequences that may ensue from participating in the research;
5. Request the (informed) consent of the participant;
6. Clearly indicate that participants are free to withdraw at any stage;
7. Clearly indicate that refusal to participate or withdrawal from the research will

not adversely affect the participant in any way;

1. Guarantee that their identity would be kept confidential;
2. Provide the name and contact details of the researcher.

### TASK 3 – Using the criteria above, consider what strategies you would use in working towards preparing a research proposal. See the feedback below for useful points to take into account.

**FEEDBACK**

Make sure you have taken account of the following strategies for retaining confidentiality:

* Inform the interviewee or participant of your purpose, process and any limits to confidentiality;
* Plan how you will record, store and process the data;
* Inform participants how you will record, store and process the data;
* Keep Informed Consent forms under lock and key;
* Destroy personal details once the data is entered on the database.

# 6 Summary

In working towards developing a research protocol/proposal towards your mini- thesis, you should have a clear sense of what lies ahead in the research process. It requires you to refine your research question and think about your aims and objectives in a rigorous way, making sure (from your literature survey) that your proposed research will make a contribution to public health.

In working towards developing a research protocol/proposal, you should also anticipate ethical issues that could arise in the course of your research. In choosing the study design, you need to consider the nature of the data that you want to collect and the target population that you will collect the data from. There are several techniques to data collection and sampling, as well as data analysis that will be covered in whichever of the Research Methods modules, the *Quantitative* or *Qualitative Research Module* that you choose to take next year.

### YOU ARE NOW READY FOR ASSIGNMENT 2 –YOU WILL NEED TO DRAW ON THE WHOLE MODULE – PARTICULARLY FROM UNIT 2- THIS UNIT FOR YOUR ASSIGNMENT. GO BACK ESPECIALLY TO UNIT 2 AND 3 ON RESEARCH PROBLEMS, QUESTIONS, LITERATURE REVIEW AIM, OBJECTIVES AND PURPOSE. THE ASSIGNMENT ALSO REQUIRES YOU TO DRAW ON THIS UNIT – UNIT 4.

**GOOD LUCK. REMEMBER TO TRY AND HAND IN A DRAFT FIRST SO THAT WE CAN GIVE YOU FEEDBACK BEFORE YOU FINAL ASSIGNMENT.**

***WE HOPE YOU HAVE ENJOYED AND LEARNT FROM THIS MODULE! PLEASE GIVE US FEEDBACK BY COMPLETING THE EVALUATION ON IKAMVA WHEN YOU HAVE COMPLETED THE MODULE.***

# References

Cash, R., Wikler, D., Saxena, A. & Capron, A. (2009). Ch 1 – What is Research? In *Casebook on Ethical Issues in International Health Research*: Geneva: World Health Organization: 38.

[Available at: whqlibdoc.who.int/publications/2009/9789241547727\_eng.pdf]

Cash, R., Wikler, D., Saxena, A. & Capron, A. (2009). Ch 4 – Voluntary Informed Consent. In *Casebook on Ethical Issues in International Health Research*. Geneva: World Health Organisation: 83 – 92.

Polit, D. E. & Hungler, B. P. (1993). Ch 5 - The Ethical Context of Nursing. In *Essentials of Nursing Research, Methods, Appraisal and Utilization*. Philadelphia: J. B. Lippincott Company: 125-147.

Wassenaar, D. (2007). Ch 4 - Putting Design into Practice: Writing and Evaluating Research Proposals. In Terre Blanche, M. & Durrheim, K. *Research in Practice: Applied Methods for the Social Sciences.* (Eds). Cape Town: UCT Press: 65 - 71**.**