Nursing and Midwifery Research
methods and appraisal for evidence-based practice
5th edition

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# Contents

Contents
Foreword v
Preface x
Editors xi
ANZ Contributors xii
US Contributors xiii
Reviewers xv
Acknowledgments xvii

## SECTION 1 RESEARCH AWARENESS

1 The significance of nursing and midwifery research and evidence-based practice 3
   Zevia Schneider and Dean Whitehead
   Introduction 4
   How does research knowledge influence our practice? 4
   Background to evidence-based nursing and evidence-based midwifery 5
   Research awareness and consumerism 5
   What is evidence? 5
   Linking theory, education and practice to nursing research 6
   International and Australasian nursing research—a brief history 7
   International, Australian and New Zealand journals 9
   Educational preparation for conducting research 9
   Promoting nursing and midwifery research 11
   Research roles 11
   An unexpected hurdle 12
   Collaborative research teams 12
   Clinical governance and clinical audit 13
   Future directions for nursing and midwifery research 13
   Summary 14
   Time to reflect 14

2 An overview of research theory and process 19
   Karen Francis, Ysanne Chapman and Dean Whitehead
   Introduction 20
   Research theories, philosophies and paradigms 20
   Choosing a paradigm 24
   An unexpected hurdle 26
   Theoretical and conceptual frameworks 26
   Research process and research design 27
   Summary 29
   Time to reflect 29

3 Ethical and legal issues in research 33
   Martin Woods and Richard Lakeman
   Introduction 34
   A brief background to ethical and legal considerations in research 34
   Core principles 36
   An unexpected hurdle 44
   Researcher integrity and honesty 45
   Legal and ethical regulatory mechanisms 46
   Summary 48
   Time to reflect 48
## 4 Searching and reviewing the research literature

*Dean Whitehead and Phillip Maude*

| Introduction | 54 |
| The influence of the digital ‘internet age’ | 54 |
| Types of research literature sources | 55 |
| Assessing the quality of listed journals | 59 |
| Conducting a search of the research literature | 59 |
| Reporting the search strategy | 61 |
| An unexpected hurdle | 63 |
| Managing the collected research literature | 63 |
| Reviewing the research literature | 63 |
| Summary | 68 |
| Time to reflect | 69 |

## 5 Identifying research ideas, questions, statements and hypotheses

*Zevia Schneider*

| Introduction | 74 |
| Developing and refining a research idea | 74 |
| Defining a specific problem area | 75 |
| The significance of research problem statements to nursing or midwifery | 76 |
| Reviewing relevant literature | 79 |
| Operational definition | 82 |
| An unexpected hurdle | 83 |
| Hypothesis testing | 83 |
| Summary | 86 |
| Time to reflect | 87 |

### SECTION 2 APPRECIATION AND CONSUMERISM

## 6 Common qualitative methods

*Dean Whitehead, Sophie Dilworth and Isabel Higgins*

| Introduction | 94 |
| Why is qualitative research important? | 94 |
| An emerging trend in qualitative research | 95 |
| ‘Traditional’ approaches to qualitative research | 96 |
| An unexpected hurdle | 102 |
| Other qualitative methodologies | 103 |
| Keeping up with qualitative developments | 104 |
| Summary | 105 |
| Time to reflect | 105 |

## 7 Sampling data and data collection in qualitative research

*Dean Whitehead and Lisa Whitehead*

| Introduction | 112 |
| Sampling techniques and procedures in qualitative research | 112 |
| An unexpected hurdle | 115 |
| Data collection in qualitative research | 115 |
| Summary | 123 |
| Time to reflect | 123 |

## 8 Analysing data in qualitative research

*Thomas Harding and Dean Whitehead*

| Introduction | 128 |
| Key issues in the analysis of qualitative data | 128 |
| Conducting qualitative analysis: general principles | 130 |
| Managing data analysis | 132 |
| Writing up data analysis | 133 |
| Methods of data analysis | 133 |
Other styles of analysing qualitative data 134
An unexpected hurdle 135
Qualitative meta-synthesis 135
Trustworthiness 136
Reporting and disseminating qualitative data findings 137
Summary 138
Time to reflect 139

9 Common quantitative methods 143
Linda Shields and Wendy Smyth
Introduction 144
Levels of evidence 144
Concepts underpinning quantitative research 145
Observational designs 147
An unexpected hurdle 149
Quasi-experimental designs 153
Experimental designs 156
Summary 159
Time to reflect 160

10 Sampling data in quantitative research 165
Murray Fisher and Judith Fethney
Introduction 166
Sampling concepts 166
An unexpected hurdle 169
Types of samples 169
Summary 176
Time to reflect 177

11 Quantitative data collection and study validity 181
Cliff Da Costa and Zevia Schneider
Introduction 182
Measuring a variable of interest 182
Conceptual and operational definitions 182
Types of data collection 183
An unexpected hurdle 189
Study validity 190
Summary 193
Time to reflect 194

12 Assessing measuring instruments 197
Brigid M Gillespie and Wendy Chaboyer
Introduction 198
Measurement error 198
Performance characteristics of an instrument 199
An unexpected hurdle 202
Developing a measuring instrument 207
Assessing instruments 208
Summary 209
Time to reflect 209

13 Analysing data in quantitative research 213
Murray Fisher and Judith Fethney
Introduction 214
Descriptive statistics 214
Levels of measurement 214
Measures of central tendency 216
Measures of variability or dispersion 219
Normal distribution 220
Inferential statistics 222
An unexpected hurdle 227
Summary 232
Time to reflect 233

14 Mixed-methods research
Dean Whitehead and Jenny Day
Introduction 238
What is mixed-methods research? 238
Triangulation and mixed-methods research 238
The value of mixed-methods research 241
Limitations associated with mixed-methods research 242
Action research 242
An unexpected hurdle 246
Delphi technique 247
Case study approach 249
Q methodology 249
Summary 251
Time to reflect 251

15 Indigenous approaches to research
Sandy O’Sullivan, Barbara Hill, Maree Bemoth and Susan Mlcek
Introduction 258
Understanding research in Indigenous contexts 258
Indigenous Australia: the trouble with names 259
Elders, protocols and advice 260
Understanding Indigenous contexts in health research 261
Relating cultural competence to Indigenous research and ethics 263
An unexpected hurdle 265
What does culturally competent research look like? 265
What does a culturally competent researcher ‘look like’? 267
Summary 271
Time to reflect 272

16 Critically reviewing research studies
Zevia Schneider
Introduction 278
Critical reading 278
Critical review of qualitative research studies 281
An unexpected hurdle 291
Critical review of quantitative research studies 291
Summary 306
Time to reflect 307

17 Applying research knowledge: evidence-based practice development and knowledge translation
Craig Lockwood and Alan Pearson
Introduction 312
Applying research knowledge 312
Evidence for nursing and midwifery practice 312
The development of evidence-based healthcare 313
Models of evidence based healthcare 315
Getting evidence into practice 318
Capacity-building for evidence-based practice 318
An unexpected hurdle 320
Summary 322
Time to reflect 323
SECTION 3 CONDUCTING PRIMARY RESEARCH

18 Writing proposals and grant applications
Jeffrey Fuller and Zevia Schneider
Introduction 330
What is a research proposal? 330
Planning a project 330
Writing a proposal 333
An unexpected hurdle 336
Common mistakes in proposals 341
Submitting a proposal for review 341
Research committee review and HREC review 341
Funding sources 342
Summary 342
Time to reflect 343

19 Managing a research project
Ruth Endacott and Dean Whitehead
Introduction 348
Getting involved 348
Managing a research team 349
Managing research participants 352
An unexpected hurdle 355
Managing the study data 355
Managing the budget 357
Managing a multi-national project 358
Writing project reports and publications 358
Completing the study 359
Summary 359
Time to reflect 360

20 Writing and presenting research findings for dissemination
Dean Whitehead and Zevia Schneider
Introduction 364
The importance of disseminating research findings: ‘publish or perish’ 364
How useful is disseminated information for practice? 365
Developing a dissemination plan 366
Barriers to publishing 366
Overcoming the barriers towards publication 367
An unexpected hurdle 369
The process and structure of writing for peer-reviewed publication 370
Other forums for research dissemination 374
Summary 375
Time to reflect 376

21 A research project journey: from conception to completion
Dean Whitehead and Emma Dresler
Introduction 382
The study project—Chapter-by-chapter 382
An unexpected hurdle 387
Summary 391
Time to reflect 392

Glossary 395
Index 403
Foreword

I am pleased to introduce this fifth edition of Nursing and Midwifery Research: methods and appraisal for evidence-based practice. The text has become a highly regarded guide to research in nursing and midwifery throughout Australia and New Zealand. This edition has retained the strength of previous editions, especially in guiding the reader from the foundations that justify our appreciation of, and professional need for, research in practice, to the finer details of conducting research studies. Also, like the previous edition, this version promotes the notion of accountability for clinical decisions embedded in the notion of professional empowerment. Empowerment is encouraged from the beginning of the book in the emphasis on understanding research as a basis for evidence-based practice.

This fifth edition has some changes, primarily in strengthening the individual chapters with contemporary examples of research and evidence-based practice and the ‘Time to reflect’ summaries for each chapter with their strong emphasis on clinical practice. Ethical and legal issues are positioned early in the process of considering a research project, and explained with remarkable clarity and relevance to healthcare systems. The new chapter on Indigenous approaches to research is extremely useful in directing our gaze to the particular issues that should be considered in these and any other intercultural partnerships. Features of this edition also include updated information on searching and critiquing literature and innovative designs and considerations in specific research approaches that are informed by the work of international scholars. As in the last edition, the tables listing advantages and disadvantages of various methods, and criteria for evaluating different types of studies, provide clarity for the undergraduate struggling to make sense of what is virtually a new language for practice, as well as prompts and reminders for postgraduate students and experienced researchers. The ‘Research in brief’ examples throughout this book are excellent. These outline the depth and breadth of research being conducted in nursing and midwifery throughout global professional networks with a strong emphasis on the advancement of research knowledge by Australian and New Zealand scholars. Tutorial triggers and learning activities continue to inform the educational approaches best suited to inspiring learners. The ‘Unexpected hurdles’ found throughout the chapters are innovative, and help dispel the notion that research is conducted without any ‘bumps in the road’. These examples help us recognize that perseverance is a crucial element in conducting and publishing a successful research study. The information on writing and publishing is current and comprehensive with detailed information that will help the novice writer ensure that findings are appropriately disseminated. The final chapter consolidating the main topics from each of the previous chapters is another welcome addition to the text that will be helpful to novice as well as experienced researchers. This chapter provides a roadmap of the various issues that must be considered at each step of the research journey.

This edition has attracted a large number of highly regarded scholars, and each is to be congratulated on the precision, clarity and inspiration they provide. I expect their words to create a new generation of committed researchers while providing the breadth and depth of understanding sought by existing researchers.

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Preface

In the years since the first edition of this book, nurses and midwives (as conductors and consumers of research) have continued to champion the need for critical appraisal and evaluation of research studies and reports. The ever-increasing impetus behind basing practice on research evidence continues unabated—as does the importance of including all nurses and midwives in the research process, through either the conduct of primary research or the implementation of findings into practice. Effective knowledge of research methodology, process and design is mandatory in today’s healthcare arena. All nurses and midwives need to understand what research findings mean and their implication for defending, challenging and changing practice.

This fifth edition is dedicated, as were our previous editions, to all health professionals and all consumers of research and those conducting research. This edition differs from previous editions in a number of respects. The changes reflect dynamic responses to the reviewers of the new edition, market events and feedback from the Australian and New Zealand readers of the previous edition. We have included two new chapters that ensure this is the most comprehensive edition to date. We have added two new pedagogical features—‘Time to reflect’ and ‘An unexpected hurdle’—to further engage readers. We have also revised some of the previous edition’s pedagogical features. As usual, we have updated both supporting citations and the primary research sources used to illustrate latest developments in the field.

We gratefully acknowledge the contribution of students, colleagues and reviewers of this text in making this edition more inclusive and broader in scope while maintaining a detailed account of the ever-changing nature and variety of the most common research approaches in our disciplines.

This edition comprises 21 chapters in three sections. Section 1, Research awareness, establishes the importance of nursing and midwifery research and provides an overview of research theory and its underpinning processes. It also includes chapters on critically searching for and reviewing the research literature and ethical and legal research issues—focusing on Australia and New Zealand. Also included is a chapter detailing how to identify and develop research ideas and questions.

Section 2, Appreciation and consumerism, provides a detailed discussion of qualitative, quantitative and mixed-methods research approaches with many useful examples from various clinical settings. Chapters are devoted to critical evaluation, implementation, sampling, collecting and analysing data in qualitative and quantitative approaches, assessing measuring instruments and applying research knowledge through evidence-based practice and knowledge translation. The section includes a new chapter on Indigenous approaches to research. Aligned to the sentiment of this new chapter is the acknowledgment of increasing internationalisation of educational programs throughout Australasia. Many practitioners enrolling in undergraduate, postgraduate and specialised clinical programs are CALD ( Culturally and Linguistically Diverse) students. A major undertaking in this text, where possible, has been to make the language of research and evidence as accessible as possible.

Section 3, Conducting primary research, is designed to enhance the previous two sections through supporting both undergraduate and postgraduate students in their ‘physical’ research activities. Writing research proposals may be a requirement for undergraduates in their research program (especially at the Honours level) and postgraduates will find the information useful for developing an ethics proposal or applying for university and/or external funding. Research project management is included in this section, as is useful advice on how to present research findings—especially through the process of publication. The section concludes with another new chapter, which is designed to bring the whole research process together by describing the beginning-to-end processes of a recently completed research project. It should be of great advantage to both those new to the research process and those who are considering initial stages of conducting research in the field.

We hope that you enjoy using the fifth edition of this text and that it stimulates and encourages you to read and think about research and its place in your professional practice. We also hope it assists in the development of your skills and confidence in critically searching for and appraising the research literature. Most importantly, we hope that you will share your information about research with your colleagues and use research findings to inform the care that you deliver to your patients and clients. The delivery of quality nursing and midwifery evidence-based care is a challenge in our dynamic healthcare environment. Used appropriately, this text will be a valuable tool to assist you in that process.

Zevia Schneider and Dean Whitehead
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The fifth edition of Nursing and Midwifery Research has undergone a number of changes. Two new chapters have been added: Chapter 15, 'Indigenous approaches to research', is a direct response to insightful feedback from colleagues in line with a moral and ethical duty to include indigenous populations and 'their' research. It is written in the spirit of indigenous rights as an integral representation of the Australian and New Zealand tapestry—without which the research picture would be incomplete. Alongside this, internationalisation processes have enriched our practice and we intentionally acknowledge that contribution to our research culture with respect and gratitude throughout this book. Chapter 21, 'A research project journey: from conception to completion', attempts to summarise and 'capture' the essence of all the chapters in this book by detailing the processes of a specific recent research project. It is designed to provide a detailed map for beginning researchers to get a feel for how 'typical' well-constructed research process begins, unfolds and concludes.

Our appreciation is extended to all of our contributors for their collegiality and support and also to each other for creating a friendly, supportive and cooperative environment in which to achieve our aims of producing a market-leading text in the important field of nursing and midwifery research.

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We gratefully acknowledge the copyright holders for allowing us to reproduce their works in the text.

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Zevia Schneider and Dean Whitehead
Chapter 3

Ethical and legal issues in research

Martin Woods and Richard Lakeman

Learning outcomes

After reading this chapter, you should be able to:

• briefly outline the key events that led to the development of ethical codes and regulations for the conduct of research involving human participants
• describe the principles of ethical research involving human participants
• identify responsibilities of the researcher in research governance
• identify the laws, regulations and codes that apply to the conduct of research in Australia and/or New Zealand
• explain the key elements of a written consent form for prospective research participants.

Key terms

anonymity
autonomy
beneficence
code of ethics
confidentiality
cultural diversity
human research ethics committee (HREC)
human rights
informed consent
justice
privacy
respect for persons
risk/benefit
vulnerable participants
INTRODUCTION

Research, like healthcare, often has profoundly moral and legal dimensions, in a large part because of the great potential for benefit or harm that can arise from its use. In this chapter we are largely concerned with research involving human beings. What constitutes a person or a citizen is perhaps contestable, but we can generally agree that a human is a human regardless of stage of development, degree of functioning or level of consciousness. People have their own interests as researchers, participants or as parts of collectives such as professions, academies, businesses, societies, and cultures. People often assume multiple roles, are bound by duties and responsibilities, have their own (and collective) agendas, and complex multifaceted relationships with each other. This is what makes research involving humans and especially health-related research not only deeply fascinating but imbued with legal and ethical problems that are different from other forms of research.

Ethical and legal issues in research are primarily concerned with the protection and maintenance of important moral values such as human dignity, autonomy, privacy, and bodily and personal integrity (Emanuel et al. 2011). The main purpose of this concern is to protect research participants by ensuring the absence or minimisation of harm, trauma, pain, anxiety or discomfort during any research project involving human beings. Many factors influence and impact on the conduct of research, and especially upon any research involving human beings. Ethical codes and legal regulations are regularly updated and amended to try to ensure the protection of participants in research studies and that research findings are shared for the betterment of others (see Table 3.1 for regulations related to health research). Nurses and midwives should be aware of their direct responsibility in research governance and ethics. Whether functioning as researcher, research assistant or health service provider the nurse or midwife is often highly attuned to people's vulnerabilities and ideally positioned to be an advocate on behalf of others. It should also be noted that as both nursing and midwifery practices continue to be increasingly research-based, it follows that both professions need to be very familiar with requirements regarding good research governance, and alert to the potential ethical and legal problems inherent in the choice of research question, design, methodology, undertaking, analysis and dissemination of research findings.

This chapter provides a brief background of the development of ethical guidelines and the state of present-day international and national efforts to maintain high ethical standards in research involving humans. Discussion regarding the nature of ethical and legal issues relating to research is then provided followed by an in-depth examination of the moral principles that guide ethical decision-making in research (illustrated with examples). A number of important aspects relating to the maintenance of good research practices that meet the standards of researcher integrity, legal and regulatory requirements and of some ethics committees follow. Finally, there is discussion regarding the evaluation of a research project from an ethical viewpoint.

A BRIEF BACKGROUND TO ETHICAL AND LEGAL CONSIDERATIONS IN RESEARCH

The development of codes of conduct and systems of ethical review and oversight of health-related research has largely been driven by concern following a number of major human rights infringements throughout the twentieth century. One highly significant catalyst for change was 'medical research' associated with Nazism in Europe prior to, and during, the Second World War. The Nuremberg trials that occurred after the war uncovered a large amount of extremely disturbing material that revealed that health professionals were involved in unconscionable, criminal and scientifically flawed experiments on prisoners (Taylor 1946; Trials of war criminals before the Nuremberg Military Tribunals 1949). As a result of these trials, the Nuremberg Code was established (1949). This code offered a set of ethical principles that were intended to apply to all future research involving human beings. However, in the decades after these trials, other highly dubious research projects involving humans have also emerged; for example, the Vipeholm experiments (1940s–50s) on dental caries involving the 'mentally subnormal', Milgram's (1963) experiments on obedience involving members of the general public, Zimbardo's (1971) Stanford prison experiment on the effects of social control, and the infamous 'Tuskegee Syphilis Trial' (Tuskegee Syphilis Study Legacy Committee 1996) where members of a large community of African-American people in southern USA were never told that they had syphilis so that its natural progression could be researched (Tolich & Davidson 2011). More recently, a growing number of dubious pharmaceutical trials have called into question conflicts of both economic and social interests in research involving humans (Gøtzsche 2013).

International efforts to reach agreements on what constitutes ethical conduct in health research culminated in the Declaration of Helsinki adopted by the World Medical Association (WMA) in 1964 (and modified over
ensuing decades). The declaration provides advice regarding the design and performance of each research study and mandates that research be clearly formulated in a protocol and submitted to an independent ethics committee for review, comment, guidance and approval. The most recent version of the Declaration of Helsinki (WMA 2013) still contains key ethical principles that add to those in the Nuremberg Code and earlier versions of the Helsinki Declaration, including (amongst others) the medical researcher’s duty to protect the life, health, privacy, autonomy and dignity of the human participants (see www.wma.net/en/30publications/10policies/b3/index.html for a full description of the principles). This declaration has provided a template for the regulation of ethical conduct of research in both Australia and New Zealand, as in the Australian National Health and Medical Research Council’s Statement on Human Experimentation (first produced in 1966, with subsequent guidelines and revisions [NHMRC 2007]) and subse- quent guidelines such as the National Statement on Ethical Conduct in Research Human Research (2007a).

It is salutary to note, however, that even in New Zealand, a signatory to the Helsinki Declaration itself, dubious research practices were revealed in the 1980s at the inquiry into the research practices at National Women’s Hospital in Auckland (Cartwright 1988). The study aimed to prove that untreated carcinoma in situ (CIS) would not progress to become invasive carcinoma and women were entered into a two-group trial: 817 had the standard treatment (i.e. surgery) and 131 were mainly monitored annually but had no major surgery performed on them. Much later, an independent review of the data found that the women who continued to produce abnormal cytology after 2 years of follow-up had four times the risk of developing invasive cancer, and that at least 29 of the women had indeed developed invasive cancer leading to their premature deaths. (See www.cartwrightinquiry.com for information about the public enquiry and changes to medical and research ethics in New Zealand.)

Finally, it is important to recognise that in an effort to prevent further unethical biomedical research, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) continues to define high standards of integrity, responsibility and accountability in research. The most recent international declaration adopted by UNESCO is the Universal Declaration on Bioethics and Human Rights (UNESCO 2005). The aims of this declaration include providing a universal framework of principles and procedures to guide countries as they develop legislation and policies and implement ethical review committees. The declaration also guides the actions of individuals, groups, communities, institutions, and public and private corporations involved in bioethics, and promotes respect for human dignity and protection of human rights and fundamental freedoms. Core principles are:

- respect for autonomy and individual responsibility (informed consent)
- respect for privacy, anonymity and confidentiality
- respect for justice, beneficence

<table>
<thead>
<tr>
<th>Table 3.1 Regulations related to health research in Australia and New Zealand</th>
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<tr>
<td><strong>Country</strong></td>
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<tr>
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</tr>
<tr>
<td>Australia</td>
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<tr>
<td>NHMRC (2007—Updated 2014) National Statement on Ethical Conduct in Human Research</td>
</tr>
<tr>
<td>NHMRC (2006) Keeping Research on Track: a Guide for Aboriginal and Torres Strait Islander Peoples about Health Research Ethics</td>
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<tr>
<td>NHMRC (2003) Values and Ethics—Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research</td>
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<tr>
<td>HRC (2014) HRC Guidance Notes on Research Ethics</td>
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<tr>
<td>NEAC (2012) Ethical Guidelines for Intervention Studies</td>
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<tr>
<td>NEAC (2012) Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities</td>
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<td>HRC (2007) Research Involving Children</td>
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</table>
respect for human vulnerability and personal integrity

- respect for cultural diversity.

These core principles may be found in nearly all relevant materials produced in many countries that support the Declaration, and most certainly in both Australia and New Zealand. Subsequently, they serve as an excellent basis for the following review of the most important ethical principles in research involving human beings.

**CORE PRINCIPLES**

**Respect for autonomy and individual responsibility (informed consent)**

Respecting a person’s autonomy (freedom to determine one’s own actions) acknowledges their right to hold views and make choices based on personal values and beliefs and acknowledges that they are capable of deciding what happens to them. A person can only exercise their autonomy if they are free from coercion, undue influence and external restraint when making decisions. Researchers need to show respectful attitudes and actions to protect the person’s autonomy (Beauchamp & Childress 2013). This means ensuring that the participant (or carer or guardian) understands such things as who is undertaking the study (and what their interests are), what the study is about, what is involved if they participate, what the risks and benefits are, how their rights and interests are protected, and more. The researcher is required to express this information in a plain language information sheet and a written consent form. This is problematic where people may have poor literacy skills or inadequate understanding of the research proposal; it follows that other ways to impart information, and gain informed consent, should therefore be utilised. Participants must have their questions answered until they are satisfied and made aware of their right to withdraw from the study without prejudice (that is, without adversely affecting their healthcare experience). They must also be allowed sufficient time for discussion with their family or significant others. In situations where the participant does not understand English, an interpreter should be used to ensure that the participant fully understands the proposed research. Understanding and consent may often need to be revisited, particularly if the research involves multiple visits, procedures or in-depth interviews. The elements of informed consent listed in Box 3.1 ensure respect for autonomy and individual responsibility and are presented to participants in the form of an information sheet (see also Appendices 1 and 2).

A researcher must determine whether a person is competent to consent before seeking their permission to participate. Competence to consent is determined by the extent to which an individual has the ability to understand sufficiently what the proposed activity involves, their ability to come to a decision about it and their ability to clearly communicate that decision. In the case of both nursing and midwifery research, such practices should obviously be closely adhered to, but in the latter case, midwives in particular should be fully aware that any disclosure of information must include benefits and risks and details of participation for both the woman and fetus (Ledward 2011).

Conditions that affect a person’s decision-making ability, such as learning disabilities, stroke, dementia or mental illness, do not necessarily mean that the person is not competent to consent; indeed, such people should
APPENDIX 1 Sample information sheet

(The information sheet is to be printed on the letterhead of the university at which you are enrolled or hospital/health service in which you are employed.)

INFORMATION SHEET

Dear ____________,

I am currently studying for my (name of degree) at (name of university). My thesis is by research. The title of my research project is:

‘Women’s experiences of pregnancy in an environment of conflicting discourses about health’

Researcher: (student’s name, department in which enrolled, university, suburb, state and postcode).

______________________________________________________________________________________________________

______________________________________________________________________________________________________

Telephone number: ______________________________

Email: ___________________________________________

Address: _____________________________________________________________________________________________

I would like to invite you to consider participating in my research project. The purpose of this exploratory research project is to discover how you experience your pregnancy, and the attitudes and meanings you give to the event. Your own interpretation and the meaning and significance you attach to this period are important in this study.

If you agree to participate, you will be asked to attend four interviews conducted at three stages during your pregnancy (8–12 weeks, 20–28 weeks and 36–38 weeks gestation), and once following the birth of your baby. Each interview will take about one hour. The interviews will be conducted at a time and place convenient to both you and me.

Please understand that you are free to withdraw from participation in this research study at any time and ask that all your records be returned to you or destroyed and not used in any way, provided that the request for destruction or return of records be made within 4 weeks of the completion of the interview.

Any complaint regarding the nature or conduct of this research may be directed to:

Ethics Liaison Officer, Human Research Ethics Committee, (name of university, suburb, state and postcode).

______________________________________________________________________________________________________

______________________________________________________________________________________________________

Telephone: ______________________________________

Yours sincerely

(Researcher’s name)
(The information sheet is to be printed on the letterhead of the university at which you are enrolled or hospital/health service in which you are employed.)

Faculty of

---

**CONSENT FORM**

**Title of Project:** *Women’s experiences of pregnancy in an environment of conflicting discourses about health*

**Name of researcher, and department address:**

---

I (name of participant) (please print) have read and understood all of the information on the ‘Information Sheet’ and any questions that I have asked have been answered to my satisfaction.

<table>
<thead>
<tr>
<th>I agree to take part in this research study on the understanding that:</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can withdraw from the study at any stage</td>
</tr>
<tr>
<td>I agree to the four interviews being taped</td>
</tr>
<tr>
<td>I agree to the use of any material which does not identify me in any way</td>
</tr>
</tbody>
</table>

I understand that I am free to withdraw from participation in this research study at any time after each interview, and ask that all my records be returned to me or destroyed and not used in any way, provided that the request for destruction or return of records be made within 4 weeks of the completion of the interview.

Should I wish to discuss my participation with someone not directly involved in the project, particularly in regard to matters concerning policies, information about the conduct of the study, or my rights as a participant, or I wish to make a confidential complaint, I may contact:

Ethics Liaison Officer, Human Research Ethics Committee, *(name of university, suburb, state and postcode)*.

---

**Telephone:** ____________________________

**Name of Participant:** ____________________________  **Researcher:** ____________________________

**Date:** _______  **Signature:** ____________________________  **Date:** _______  **Signature:** ____________________________
The essential requirement in all such cases is always to inform participants of the possible disadvantages of the proposed research are made clear at the start. Although Australia’s population is much larger, there are also small towns, localised neighbourhoods or communities that may present similar privacy challenges for a researcher.

**Confidentiality**

Maintaining confidentiality means that the identities of research participants will not be linked to the information they provide and, therefore, measures must be taken at all stages of a research project, including the obtaining of data, its analysis and its storage, to ensure this occurs. In qualitative research, maintaining confidentiality can be challenging. For example, a participant’s name should not be recorded on an audio-taped interview, and if someone other than the researcher will be transcription the interview, the participant has a right to know this and to be assured that the person transcribing will sign a confidentiality declaration. If another researcher will be examining the data to confirm the credibility of the study findings, participants should be told this when their consent is being sought.

The basic requirement of respecting participants’ identities by keeping the information they provide confidential applies equally to quantitative research, although the confidentiality issues are generally less problematic in research that focuses on statistics and aggregated data rather than on material obtained through in-depth interviews, etc. However, even then sufficient attention needs to be paid to the need for adequate confidentiality measures in such research. It is always possible that whilst particular individuals may not be recognisable, certain groups of people in a particular situation or institution may be, and the researcher has to consider their role within the institution, and their relationship towards fellow healthcare professionals. This is particularly the case when the researcher is researching their own professional group within the shared workplace (see ‘Research in brief’, below).

**Coercion** involves offering a significant reward or threatening some harm if the person does not participate. For example, students may feel pressure to participate in research conducted by academics to ensure good grades.

**Covert data collection** occurs when participants are unaware that research data are being collected. Although covert observation and data collection may be considered acceptable if undertaken in a public place, the recording of some types of activity could have harmful consequences for the individuals being observed—even if the activity is illegal.

**Deception** involves misinforming participants about the nature and purpose of any intended or actual research. Whilst it may be argued that some research designs necessarily involve some form of deception, it is still important that participants are not significantly misled or misinformed.

Anonymity can be more challenging because the researcher meets the participant face-to-face and needs to develop rapport (a relationship) with the participant in order to obtain information. This may also be the case in quantitative research. However, the participant’s anonymity can be protected by using assumed names (pseudonyms) and, in any event, the research itself is written up in a fashion that promotes confidentiality and anonymity of each participant. For example, the aim of the study by Elmir et al (2010) was to provide insight into younger women’s experiences of recovery from cancer-related breast surgery. Pseudonyms were used to identify four participants and to protect their identity, and the research was presented in such a way as to disguise any possible connection to any personal or identifying details of any of the four individuals.

However, it is sometimes difficult to guarantee absolute anonymity in all research projects, especially those involving a very small group of individuals within an agency or geographical area where personal traits or responsibilities may be recognised by others within the same boundaries. This issue is a particular problem in a country like New Zealand, where the small population and the likelihood of personal traits or activities being recognised by others may have consequences for a research participant. People who live in close proximity share so many stories that the stories themselves may give clues to an individual’s identity; even identifying a participant’s gender could compromise their privacy. Where maintaining the privacy of organisations and participants becomes particularly challenging, the use of pseudonyms may not be sufficient. In such cases, it is recommended that the possibility of the participant’s identity becoming known should be discussed with them as part of the informed consent process. Some participants may not find this to be a particular problem, but in other cases, it would be enough to prevent them from participating.

The essential requirement in all such cases is always informed consent, where all of the possible advantages and disadvantages of the proposed research are made clear at the start.
In a research study aimed at exploring the challenges of conducting an observational study of postnatal interactions between midwives and women (Burns et al. 2012), the researcher was a midwife observing in familiar midwifery settings. This raised questions regarding the influence of ‘identity’ and ‘insider’ knowledge on the conduct of such projects. The research was performed in two maternity units in New South Wales, Australia using 40 midwives and 78 breastfeeding women as participants. The research found that possessing ‘insider’ midwifery knowledge was advantageous in the ‘getting in’ and ‘fitting in’ phases of the research study, however, unanticipated role ambiguity, and moral and ethical challenges, arose as a result of this ‘insider’ knowledge and status. For instance, there were ethical problems with the level of ‘participating’ and ‘observing’ that the midwife researcher could engage in, and at both study sites there were examples of over-identification with midwifery participants, and feelings of betrayal of participant trust, regardless of the level of insider or outsider positioning.

**RESPECT FOR JUSTICE AND BENEFICENCE**

**Justice**

The ethical principle of justice requires fairness in dealing with others. In research, this means the risks and benefits of the study should be distributed fairly among participants. Randomising participants in a controlled trial goes some way to achieving these aims. For example, in a study investigating a nursing intervention after carotid endarterectomy, Middleton et al. (2005) used randomisation to allocate patients to the ‘treatment’ or ‘control’ group. The potential positive effects of the intervention were therefore as fairly distributed as possible. In the wider sense, the benefits resulting from research and its applications should be shared with society as a whole and within the international community, particularly in developing countries (UNESCO 2005).

Participants should be selected for a study because they match specific and clearly specified inclusion criteria, not because they are conveniently available or easily exploited. The women in the previously mentioned New Zealand National Women’s Hospital study were not treated fairly as they had no choice in their selection, and were unaware of the nature of the research being carried out on them.

Research proposals, information sheets and consent forms should clearly explain the participants’ involvement, research procedures and the researcher’s role and responsibilities. Research procedures should not change without the authorisation of the particular human ethics research committee and when this is granted, further consent from the participants or participant is generally required. If the researcher promises certain benefits for participating in the study, these should be detailed and provided. Such benefits could include being sent a summary of the results or reimbursement of travel costs, but care is needed in this situation because payment of larger amounts could influence the person’s decision and potentially be viewed as a possible bribe or inducement to participate.

**Beneficence**

The ethical principle of beneficence involves doing good, as well as preventing and removing potential harms (Beauchamp & Childress 2013). Harms include any out-of-the-ordinary exposure to the possibility of physical injury or discomfort, psychological injury or distress, social disadvantage, invasion of privacy or infringement of rights (NHMRC 2006). Similarly, the research topic or line of questioning may be psychologically disturbing because it induces fear, anxiety, sadness or some other distressing emotion in participants. For example, interviewing grandparents about their experience of losing a grandchild is likely to induce painful emotions in the participants. Researchers should identify potential harms or risks in the study proposal and explain what access to debriefing or professional counselling will be provided for participants both during and after the study.
However, given that it may not be possible to remove all risks from the research process, strategies to minimise risks and highlight possible benefits should be used and stated in the research protocol. Such strategies may include the:

. . . frequent monitoring of participants; presence of trained personnel who can respond to emergencies; coding of data to protect confidentiality; and "debriefing" for participants; continuing review and monitoring of data to ensure the study does not continue after the emergence of reliable evidence of reduced efficacy and/or safety, or actual harm to participants; exclusion of vulnerable individuals or groups from participating in research where necessary and justified; and consideration of whether alternative means for answering the research question are available, and whether participation by humans is really necessary.

(NHMRC 2002 p E4)

Some forms of research have the potential to produce a benefit to a patient against the context of risk. For example, a patient with cancer might choose to be part of an experimental treatment that offers some hope of remission. However, a researcher must not understate the potential risks of the experimental treatment nor overstate any potential positive outcomes. Prospective participants should be fully informed about the study, know that it is experimental and the probability of risks involved. This information should be clear to the participant before their consent is sought. If, on the other hand, the risk–benefit ratio shows that the risks outweigh the benefits, then it will be difficult to justify exposing participants to those risks. However, if the expected harms are minor then the study may still be ethically and legally acceptable because the expected benefits outweigh these lesser harms (for an example of this issue, see ‘An unexpected hurdle’). The critical-thinking decision path diagram provides an example of the kind of ethical decision-making process that may be used by researchers and members of an ethics committee in evaluating the risk/benefit of a research study (see Figure 3.1).

**Respect for human vulnerability and personal integrity**

Some groups of people are more susceptible to physical or psychological hurt or injury and are said to be vulnerable. These are people who have diminished or no capacity to protect themselves from threats to their safety or personal integrity. Respect for personal integrity involves: enhancing the person’s self-identity; paying attention to their humanness; acknowledging who they are; and treating them well. At times researchers in the past have recruited participants from the most vulnerable groups in society, such as the homeless, refugees, prisoners, gay men, children with intellectual disability, dying patients and ethnic minorities. Other vulnerable groups may include pregnant women, children and servicemen/women (or members of other organisations where strict hierarchy and regulatory procedures exist for ‘following orders’). Overall, members of vulnerable groups have at times been treated badly by researchers; their vulnerability and personal integrity have not always been respected. Concerns over the abuse of vulnerable populations in research projects continued to emerge over the last few decades. For instance, in the 1960s,
A school health nurse is part of a consortium of health professionals and interest groups which is intending to run a mental health and wellbeing campaign at local high schools in a town focusing on promoting mental health and reducing youth suicide. Local school counsellors have provided anecdotal reports that suicidal thinking is common amongst local youth and in the previous year there have been two suicides of young people that have rocked the local community. The nurse hopes to undertake a survey of young people to gauge the prevalence of suicidal thoughts within the local population and inform the discussion and campaign. Results will be fed back to the community of parents, teachers and students. An academic partner at the local university’s School of Nursing and Midwifery is helping with the study design. The academic expresses some pessimism about the project being approved by the local ethics committee as they have little experience assessing research addressing this sensitive topic.

**RESEARCH IN BRIEF**

In 1996, a severe African meningitis epidemic hit Nigeria’s northern states. Kano’s infectious diseases hospital was overwhelmed because they were dealing with a measles and cholera outbreak as well. Children were being seen and treated in overcrowded halls and corridors, and the situation was described as ‘chaotic’. Then a chartered plane flew in from the USA with doctors from one of the world’s biggest pharmaceutical companies. They had come to conduct a trial of an oral antibiotic called Trovan, which they wanted to test in children with meningitis against the ‘gold-standard’ treatment of the western world, Ceftriaxone. They took over part of the hospital and delivered the drugs to 200 children, half with Trovan and half with Ceftriaxone. After the drug trial they left, leaving behind some surplus drugs and equipment for the hospital. Doctors at the hospital were shocked that the company doctors were prepared to continue the research trial under such conditions (Boseley & Smith 2011).

**TUTORIAL TRIGGER 3.2**

- Should we always exclude any member of a vulnerable population from being a research subject?
- Sometimes it is argued that to do good we should accept the possibility of possible harm, as perhaps in the case of drug trials when there may be a degree of discomfort or unease for at least some of the subjects, but the benefits for the majority are considerable. If people are prepared to take that risk, why should we still be concerned?
- Should we ever involve participants from a ‘vulnerable population’ in any form of research that carries any possible risk for them?
- If children, both young and older ones, are to be involved in research, shouldn’t they be given the chance to accept or reject participation?
- Should those in poorer countries be used as unwilling or even willing subjects in research projects that may produce future benefits for those in richer countries?

Beecher (1966) published an article describing many examples of unethical or questionably ethical studies involving various vulnerable populations that he had identified in the published literature. In the 1970s, Jessica Mitford’s (1973) revelations about clinical experiments involving unconsenting prisoners that were organised by drug companies and doctors in the United States showed that there was ‘wilful disregard’ for human rights. Although the World Medical Association had recommended that prisoners, being captive groups, should not be used as participants in experiments, researchers disregarded this advice. In the 1980s and 1990s legal and ethical pressure mounted in several developed countries to protect vulnerable populations. Some researchers ‘recruited’ subjects in developing nations because disadvantaged or economically challenged communities are easier places to perform unethically conducted clinical trials (see ‘Research in brief’). Hence, even now, concerns are still being raised about the use of vulnerable populations such as children (Millum & Emanuel 2007), and the proliferation of dubious health-related research projects in developing or overpopulated countries (Chattopadhyay 2012; Igoumenidis & Zyga 2011; Srinivasan & Nikarge 2009).
experiments), within the pharmaceutical industry (as occurred in the infamous Thalidomide scandal of the late 1950s and early 1960s), and unethical drug trials in Third World countries (as previously discussed). Such scandals continue to emerge and, only fairly recently, a leading heart specialist was dismissed from Erasmus University in Rotterdam for damaging the institution’s academic integrity by faking academic data and compromising patient trust. In particular, it was maintained that he failed to obtain patient consent for carrying out research (Retraction Watch 2011).

Concerns about the increasing incidence of scientific misconduct in research have resulted in the development of regulatory bodies to advise, monitor and oversee research projects involving humans in many countries. For instance, in both Australia and New Zealand, such bodies have considerable statutory and regulatory support and control (see later discussion under ‘Legal and ethical regulatory mechanisms’). Nevertheless, the continued existence of scientific fraud and failure of peer reviews (Bohannon 2013; Nylenna & Simonsen 2006) demonstrates that national guidelines and financial inducements to obtain approval from ethics committees are not entirely sufficient. There is also increasing recognition of the ethically problematic relationship that the pharmaceutical and medical device industry has, not only as sponsors of research in which they have a commercial interest, but also in the relationship the industry has with clinicians including nurses and/or midwives. They have been accused of the selective reporting of research findings that are favourable to their products, and the general influence on behaviour and attitudes of health professionals towards using and promoting their products. There are numerous examples of potential biases in nursing publications related to undeclared conflicts of interests (Lakeman 2010).

Finally, there is considerable evidence that nurses are increasingly aware of the dangers of research misconduct in the clinical environment (Habermann et al 2010). Indeed, even though there is a possibility that a few nurses may still be implicated in charges of scientific misconduct through an association with medical researchers, most are considered socially responsible and ethical researchers.

**LEGAL AND ETHICAL REGULATORY MECHANISMS**

While there is international agreement about ethical considerations in research involving human beings, there is evidence that ensuring strict adherence to the guidelines may be problematic. For instance, in regard to the cervical cancer scandal in New Zealand in the 1980s (previously noted), Judge Cartwright found that an institutional committee failed to adequately either review the scientific merit of the study or protect the participants (Cartwright 1988). Consequently, the judge recommended that national ethical standards be developed and independent ethics committees be set up to review all health research proposals and experimental treatments. Such recommendations have been reflected in the legislation and national policies of numerous countries in recent decades, partly because those countries have themselves experienced national scandals involving unethical research projects, and partly because of the development of human rights and health-related legislation that protects research participants. Overall, in both Australia and New Zealand, research-focused law reflects concerns about traditional areas such as consent, contract, negligence and intellectual property (copyright), but other laws have a much broader focus that extend well beyond research; for example, privacy and human rights. They also have important implications for the conduct of research and research relationships. Importantly, there are specific laws in these countries that establish and regulate public research funding and/or monitoring agencies (see Box 3.4).

In summary, there are statutory organisations (councils) in both countries that provide advice on ethical issues of national significance regarding health-related research, determine nationally consistent ethical standards and provide scrutiny for such research and services. Essentially, all research that directly involves humans (or animals) should be assessed by a recognised research committee (i.e. educational or health-related) either in a full submission or, for low-risk projects, in a low-risk submission or expedited review, before the research project may proceed. The researcher remains
answerable to the respective ethics (human or animal) committee that has the authority to stop a project should concerns about the conduct of the project emerge.

Evaluating and monitoring ethical issues in nursing research

Professional nursing organisations have a role to play in guiding nurses and midwives in the practice of research. In Australia, the Standards for Research for the Nursing Profession were developed in the 1990s as guidelines for registered nurses and midwives undertaking research, and more recently, the Australian Nursing Federation (ANF) has produced an updated policy document on the same topic (ANF 2012; see http://anmf.org.au/documents/policies/P_Nursing_Midwifery_Research.pdf). These standards provide the structure for ensuring accountability for nursing research for the profession and the community and are complementary to the NHMRC (2002) and HRC (2005) guidelines. The National Statement on Ethical Conduct in Human Research (NHMRC 2007a) reflects overall governance of research in Australia, providing guidelines for researchers, HRECs and those engaged in the ethical review of research. In New Zealand, any nurse considering research involving humans is advised to first view the National Ethics Advisory Committee Guidelines (www.ethics.health.govt.nz) before proceeding with either a local (i.e. institutional) or a national (i.e. Health and Disability Ethics Committees [HDECs]) ethics proposal.

The roles of both general and specific guidelines for the ethical conduct of research and the institutional research and ethics committees cannot be overstated: both are vitally important safeguards. Sometimes, research studies published in professional journals do not provide the research consumer with detailed information regarding the ways in which ethical procedures were adhered to. This does not necessarily mean that the research was unethical. In the absence of documentation regarding ethical issues, the acknowledgment that the research study was approved by an external HREC should assure the reader that the proposal was reviewed and permission given to proceed with the study. However, all published research should be carefully scrutinised for reasonable evidence of ethical soundness by the nurse or midwife reader, because authors, editors and publishers all have ethical obligations with regard to the publication of the results of research, including a duty to make publicly available the results of their research on human subjects, and an accountability for the completeness and accuracy of their reports (WMA: Declaration of Helsinki 2013).

Any published research that does not appear to have HREC or even perhaps institutional ethics approval, is incomplete or vague, or does not appear to contain any negative or inconclusive results (or at least research limitations), is therefore suspicious, but not necessarily unethical. However, because it is possible that someone may wish to replicate a research project, or act upon the findings of the research, it is important that the published research is trustworthy. The detailed guidelines in Box 3.5 should assist the research consumer in evaluating the legal and ethical aspects of a research study (see also Chapter 16).
Aim: To enhance your research ethics skills.

Objective: To enable you to more fully appreciate desirable ethical requirements when researching a vulnerable population.

Reflect on the following:

You are a clinician working in an emergency department (ED) of a regional hospital. You notice that some ED attendees appear to present frequently in varying states of intoxication with a range of alcohol-related health problems. Some attend so frequently that they know you and other staff by name. You are interested in why these individuals seem to fail to address their problematic alcohol use, yet others may attend only once and not again. You obtain a small grant from your health service to explore the experience of people who present to the ED in a state of intoxication, their utilisation of after-care services and post-ED presentation drinking patterns.

KEY POINTS

- Internationally agreed ethical principles in research involving human participants are: respect for autonomy; respect for privacy; respect for justice; beneficence; respect for human vulnerability and integrity; and respect for cultural diversity.
- Informed consent procedures ensure the individual's autonomy and right to self-determination are respected.
- Respecting an individual's privacy in research involves protecting their anonymity and treating their information as confidential.
- Research misconduct involves fabrication, falsification, plagiarism or other unacceptable practices.
- Some groups of people are more vulnerable to exploitation than others and require special protection; for example, children, prisoners, service people, people with mental health and learning disability issues, pregnant women, etc.

SUMMARY

All research projects involving humans are required to be submitted to their respective institutional ethics committees before the commencement of a project. These institutional ethics committees act in the interests of research participants in order to ensure the guidelines developed by the appropriate authority (e.g. in Australia, the NHMRC, and in New Zealand, the HRC) are observed. It is important for nurses and midwives to understand exactly what is meant by ensuring the rights of participants and other individuals (including themselves) in the research process. Also, as research consumers, nurses and midwives need to critically evaluate research studies in order to decide whether ethical and legal issues have been appropriately addressed or not.

Adhering closely to ethical principles and procedures is an inherent part of the research process. Researchers are duty-bound to clearly include details of this process in their disseminated findings. Addressing ethical issues is a vital part of research design and an integral part of the overall research process.

BOX 3.5 Criteria for evaluating the legal and ethical aspects of a research study

- Was the study approved by an ethics committee?
- Did participants receive full information about the purpose and nature of the study?
- What evidence is provided to indicate that informed consent was obtained from participants?
- Was the information written and discussed in a language and at the appropriate level of understanding of the participant?
- Did the researcher clearly explain any risks and their management?
- Did the researcher discuss the risk–benefit ratio?
- Did the researcher meet legal requirements?
- Is there any evidence of harassment, inducement or coercion during the consent process?
- How was the privacy of the participants maintained?
- What special protection was in place for vulnerable participants?
- Did participants have access to the results or findings of the research study?
Chapter 3 | Ethical and legal issues in research

QUESTIONS
1. When the researcher notifies a person of any proposed participation in research, which of the following ethical requirements is most being met?
   a. respect for justice
   b. respect for privacy
   c. beneficence
   d. respect for autonomy.

2. The qualitative researcher used pseudonyms when quoting the participant’s narrative in the published study, and so met the main requirement for:
   a. respect for justice and equity
   b. respect for privacy
   c. beneficence
   d. respect for autonomy.

3. By selecting only unemployed men for the study and promising to pay them a substantial amount of money to be in the experimental group, the researcher did not meet the requirement for:
   a. respect for justice and equity
   b. respect for privacy
   c. beneficence
   d. respect for autonomy.

4. The researcher acknowledged in the information sheet that talking about experiences of the death of a child might be emotionally painful. By setting up access to counselling services for participants, the researcher met the requirement for:
   a. respect for autonomy
   b. respect for justice
   c. beneficence
   d. respect for privacy.

5. The main role of an institutional or regional ethics committee in Australia or New Zealand is to:
   a. protect research participants from harm
   b. protect the institutions involved from adverse publicity
   c. protect the researcher/s from criticism
   d. protect the funding body of the research.

6. The statement about vulnerable participants that is not true is:
   a. vulnerable participants are less able to understand what is involved if they take part in the study
   b. vulnerable participants find it difficult to understand how risky the study may be
   c. vulnerable participants cannot communicate their wishes about taking part in the study
   d. vulnerable participants are those people less likely to be harmed.

7. Research involving Indigenous Peoples has special ethical concerns because:
   a. such groups are a different culture from the rest of the population
   b. such groups have been exploited by researchers in the past
   c. such groups have leaders who may refuse access to participants
   d. such groups tend to live in remote areas.

8. Research misconduct refers mainly to:
   a. a study that has been poorly conducted
   b. a study that is unscientific
   c. errors in data analysis or interpretation
   d. fabrication or falsification of research results.

Learning activities

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