**THE NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH:**

**WHICH SECTIONS SHOULD I READ?**

**by Simon Moss**

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| **Introduction**  |

 To design and conduct research as ethically as possible—especially research that entails human participants—you should become familiar with the National Statement on Ethical Conduct in Human Research. This National Statement governs the decisions and practices of ethics committees in Australia.

 Unfortunately, during the first six months or so of the PhD or Masters by Research, candidates often feel inundated with books and articles to read. Consequently, some candidates do not read the entire National Statement during this period. Yet, because you really need to appreciate these ethical principles as early as possible, we have constructed a document to help you learn these principles as efficiently as possible. Specifically

* the following tables summarize each section of the National Statement
* the third column specifies who should read each section
* the fourth column specifies the urgency of each section.

In particular,

* low urgency usually implies the principles in this section are obvious or reinforced many times in this National Statement
* medium urgency usually implies the principles in this section are repeated elsewhere, at least occasionally
* high urgency implies that you should read this section in depth—but only if the third column indicates this section is relevant to you
* an asterisk indicates the corresponding principle is especially insightful rather than obvious

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| **Summary of the National Statement**  |

**Preliminary sections**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 1-2 | * This section highlights that researchers should consult other sources about ethics as well
 | * all researchers
 | Low |
| Pages 3-5:Preamble | * Risks in research are sometimes overlooked
* Many levels of organisations, from researchers to managers and funding organisations, are responsible for ethics
* Researchers should also read the Australian Code for the Responsible Conduct of Research
 | * all researchers
 | Low |
| Pages 6-8:Purpose, scope, and limits of the document | * Defines research as activities that generate new or improved knowledge or practices—rather than routine assessments or development of teaching material \*
* Defines human research as research conducted with or about people, their data, or their tissues
* The National Statement does not encompass legal obligations or statutory regulations
 | * researchers who are not certain whether their project is defined as human research or warrants ethical clearance
 | High |

**Section 1. Values and principles of ethical conduct**

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| Section | Main contents | This section is targeted at… | Urgency |
| Page 9Introduction | * Briefly defines the four main values: research merit and integrity, justice, beneficence, and respect for human beings
 | * all researchers
 | High |
| Page 10Research merit and integrity | * Merit entails benefit to knowledge or wellbeing
* Merit also includes research that enhances researcher capabilities \*
* Can be evaluated by peer review rather than ethics committees
* Integrity entails principles of research conduct, research honesty, and transparency
 | * all researchers
 | Medium |
| Page 10Justice | * Justice entails fairness and equality around who benefits from the research, who is burdened by the research, and who is included in the research
* As an example of injustice, researchers do not often study communities that are hard to access—and so these communities do not benefit from research \*
 | * all researchers
 | Medium |
| Pages 10-11Beneficence  | * Benefits must outweigh risks—especially if only the community, instead of the participants, benefit
* Researchers must strive to minimize and communicate risks
 | * all researchers
 | Medium |
| Page 11Respect | * Researchers should respect the welfare, beliefs, perceptions, customs, and cultural heritage of people and communities
* They should also respect privacy, confidentiality, cultural sensitivities, and agreements
* They must enable people to reach decisions or protect individuals who cannot as readily reach decisions
 | * all researchers
 | Medium |

**Section 2. Themes in research ethics: Risk versus benefit and consent**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 12-14Introduction to risk and benefit | * Risk depends on the likelihood and severity or consequences of harm, discomfort, or inconvenience
* Harms include physical injury, illness, or pain; psychological harms, distress, or embarrassment; social harms including damage to reputation, status, networks, employment, and insurance as well as humiliation; economic costs; and legal consequences
* Discomforts include minor side effects of medication or mild anxiety but not distress
* Inconvenience entails relinquishing time or effort
* These risks are not restricted to participants; other people may discover upsetting information; communities may be tarnished \*
* Research that elicits only inconvenience is defined as negligible risk
* Research that elicits only discomfort is defined as low risk
* Risks must be minimized whenever possible.
* Risks are more likely to be accepted if the participants directly benefit from the research—such as cancer trials \*
 | * all researchers
 | Low |
| Pages 14-15Guidelines | * Ethics review boards may sometimes consult people with expertise in a methodology to evaluate the likelihood, severity, and consequences of risks
* As the likelihood or severity of risks increases, researchers must be more certain they can manage the risks and that participants are aware of these risks
 | * all researchers
 | Low |
| Pages 16-18Consent | * Consent must be voluntary and predicated on sufficient understanding of both the research—the purpose, demands, risks, and benefits—and the implications of participation
* If warranted, participants should be granted opportunities to ask questions to clarify this understanding \*
* The information that participants receive should also include the right to refuse participation and withdraw at any time, payments to participants, services in response to adverse effects, how the responses will be disseminated, the sources of funding, the contact details of researchers and the ethics board
* Researchers must attempt to prevent implicit coercion, in which individuals feel obliged to participate
* For example, payment should not be so high that individuals feel compelled to participate \*
* Lawful authorities might consent on behalf of children or people with an intellectual disability, but only if participation does not contradict the interests of this participant
* In some communities, customs dictate that elders or other bodies should reach decisions about consent
* Individuals should not have to justify their decision to withdraw from the research
 | * all researchers
 | High |
| Pages 19-20: Qualifying or waiving conditions for consent: Overview | * To access health information, or other sensitive databases, researchers might need to consult the Australian Privacy Principles Guidelines
 | * all researchers
 | Medium |
| Page 20:Limited disclosure | * Sometimes, disclosure of aims or demands would compromise the research
* Limited disclosure might be approved if necessary, if the benefits outweigh the risks of limited disclosure, if the risks are low or negligible, if the aims are disclosed as soon as possible, if the limited disclosure does not increase the risk of harm, and if participants would most likely have consented had the information been disclosed \*
 | * researchers who may not want to disclose all the key aims, methods, benefits, or risks of this research to participants
 | High |
| Pages 20-21: Opt out approach | * Although uncommon, when research is futile unless most relevant individuals participate, an opt-out approach might be accepted. An opt-out approach tends to increase the sample size appreciably. \*
* Participants are assumed to consent unless they explicitly refuse
* To be approved, risk must be low, participants are granted enough information and time to opt out, and participants can seek more information if needed
 | * researchers who need almost every relevant individual—such as employees of a specific organisation—to participate
 | High |
| Pages 21-22: Waivers | * The need to seek consent may be waived if consent is impractical—provided that participants would most likely have consented, privacy has been protected, and participants will not be deprived of any financial or legal rights
 | * researchers who cannot seek consent from participants—often because they want to access data that was collected in the past
 | High |

**Section 3: Ethical considerations in the design, development, review, and conduct of research**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 23-24Introduction | * The boundary between innovative clinical practice and research is sometimes hazy; but ethics committees should be informed of major innovations, even if these innovations are not strictly research
* Any research that entails Aboriginal and Torres Strait Islander peoples should be governed by the “Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders”, “Keeping research on track II” and the “Guidelines for Ethical Research in Australian Indigenous Studies”
 | * researchers whose research revolves around clinical practice or Aboriginal and Torres Strait Islander peoples
 |  High |
| Pages 25-26: Elements of research—Introduction | * Researchers have sometimes developed other skills, such as counselling skills; whether they should apply these skills with participants may demand careful consideration of implications
 | * all researchers
 | Medium |
| Pages 26-28: Research scope, aims, themes, questions, and methods | * Researchers need to justify the benefits of their research—to knowledge, to improvements in wellbeing, or to the expertise of researchers—with reference to past literature if possible
* Researchers should clarify how their methods fulfil these aims and culminate in valid and reliable results
* Sometimes, the experience, insights, and needs of participants will inform the results.
* When the research is designed to assess some intervention that could affect the health of participants, all participants must at least receive treatment as usual or better. No control condition, for example, should entail the absence of treatment \*
* Whenever possible, researchers should register all clinical trials on a publicly accessible register \*
* Some designs comprise a series of stages. Later stages might depend on the results of previous stages. For these designs, describes known procedures as well as how they intend to seek ethics for each stage.
 | * all researchers
 | Medium |
| Pages 28-30: Recruitment | * Some communities are subjected to excessive levels of research; researchers should be cautious when recruiting participants from these communities and guarantee these communities benefit commensurably \*
* Researchers sometimes shun research on communities that demand special provisions, such as Indigenous communities; this tendency may be unfair, because these communities might not benefit from research sufficiently
* When researchers exclude specific people from the sample, they might unfairly prevent some individuals from enjoying the benefits of this research—a form of discrimination \*
* The procedures that are utilized to recruit participants must respect their culture, traditions, and beliefs as well as maintain the privacy of individuals
* Sometimes, researchers need to seek approval from relevant communities or organisations before they attempt to recruit individuals
* If researchers engage people who are unfamiliar with the National Statement to recruit participants, they still need to demonstrate how they can be sure these people will comply with the code \*
 | * all researchers
 | High |
| Pages 30-32: Consent | * Researchers can organize consent of a specific activity or an ongoing program
* Information about the project must use language and methods that are appropriate, respectful, and relevant to the culture of participants and the features of this research
* Researchers might need to apply more than one strategy to seek consent for each cluster of participants
* Consent may also need to be revisited and renegotiated over time—and might entail successive phases \*
* Consent may not always entail written information and forms—but should usually be as simple as possible
* Researchers must grant participants enough time to contemplate consent
* Researchers need to disclose to participants whether anyone else, including supervisors, are aware of whether these individuals have been approached and have agreed to participate
* Researchers should explain the effects of refusal to participate or withdrawal from the study—and these effects should not be detrimental
* Researchers should clarify how the data will be utilized, such as whether the data will be stored in a repository, used in future projects, or reported to relevant authorities and how participants can receive a summary of the results
* When the research is a health intervention, even more information needs to be disclosed, such as access to the treatment after the research ends and whether the treatment is novel or has been used to treat other conditions
 | * all researchers
 | High |
| Pages 32-35: Introduction to collection, use, and management of data and information | * The word “data” tends to refer to bits of information in their raw form—but can still include cleaned, transformed, summary, and meta-data
* The word “information” refers to data that have been interpreted, analysed, and contextualized.
* Risks are greater when people could relate the data or information to a specific participant—from various details, such as addresses, or from a code book. In practice, the extent to which a person can be identified varies across a continuum—and may depend on access to technology and so forth
* Many considerations, such as whether the participants are famous or members of small communities, determines identifiability
* Because of machine learning, data breaches, and other events, data in government and private datasets may be more identifiable than researchers first realise. Participants should be warned of this possibility—and informed how their privacy will be maintained \*
 | * all researchers
 | High |
| Pages 35-36 Data management  | All the researchers on a project should agree on a data management plan that specifies * how the data will be collected, stored, destroyed, shared, and used
* the systems and technologies that will be utilized to maintain security—proportionate to the risks and sensitivity of this information
* how the relevant individuals will be trained to follow this plan
* licencing of data and confidentiality agreements
* strategies to manage the risks associated with these activities.
* Biological materials should be preserved and recorded long enough to notify relevant individuals if health problems are identified
* Whenever ethical, researchers should strive to maintain data long enough to be used in future research projects \*
 | * all researchers
 | High |
| Pages 36-37Secondary use of data or information | * Researchers sometimes want to use administrative data—data routinely collected as part of some other service; researchers cannot readily seek consent from the participants to use these data

Instead, to demonstrate respect towards participants, researchers could * consult the relevant communities
* show the research will improve these services—and thus aligns to the interests of these participants
* acknowledge the source of these data in publications
* Some data on the internet, such as posts and tweets, might be publicly available, but participants had assumed the data were private
* Hence, these participants might not have granted permission, either explicitly or implicitly, for researchers to use these data
* Terms and conditions on social media could also guide how data or information on these platforms could be used \*
* Unless a waiver is obtained, researchers should use data in accordance with the consent that was granted.
* Researchers should not use information that was obtained unethically or illegally
 | * researchers using data that had been collected for another purpose
 | High |
| Pages 37-38: Sharing of data or information | * Data or information may be stored in a repository, like an archive, that other researchers could access
* An assigned person or agency needs to be the custodian or manager of these data
* Researchers must ensure these custodians comply with the data management plans, confidentiality agreements, and other conditions that relate to the identifiability or re-use of data
* Data management plans should distinguish how they share data with specific third parties, researchers in general, and the public
* Sometimes, participants can provide extended or unspecified consent to use the data indefinitely
* If this extended consent was not arranged, but researchers want to use these data in the future, they might seek a waiver on consent—especially if the burden on participants or researchers to obtain consent would be disproportionate
 | * researchers who might want to share the data with other researchers
 | High |
| Pages 38-39:Communication of researchfindings or results to participants | Whether results should be communicated to participants or other third parties depends on a variety of considerations such as * the extent to which the results could enhance the wellbeing of participants
* the degree to which participants expect they will receive the results
* Often, researchers may communicate the aggregate results to participants—such as averages across the sample
* But, especially if relevant to the health of participants or relatives, researchers may communicate individual results to each person
* Whenever applicable, researchers should enable participants to choose whether they—or someone else, like a clinician—receives the results or not \*
 | * all researchers
 | Medium |
| Pages 39-40: Disclosure to third parties of findings | * Sometimes, researchers are legally, contractually, or morally obliged to disclose specific findings to a third party—like a court or doctor
* Researchers should balance the risks and benefits of these disclosures
* If possible, researchers should often forewarn participants of potential disclosure
* If researchers are unexpectedly ordered to disclose information—such as to a court—they should seek advice from the ethics review panel on how to manage this request \*
 | * researchers who might need to disclose the data or findings to a third party, such as a court
 | High |
| Page 40: Dissemination of projectoutputs and outcomes | * The output and outcomes of research should be published and thus accessible—consistent with the principles of beneficence and merit—even if the results are inconclusive or unwelcome \*
* Some risk factors or commercial interests might justify a delay or restriction in publication
* These publications should be as comprehendible as possible to participants
 | * all researchers
 | Medium |
| Page 41: After the project | * If data and information are culturally or historically significant, they may need to be retained beyond the minimum retention period, such as more than 5 years
 | * all researchers
 | Medium |

**Chapter 3.2: Human biospecimens in laboratory based research**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 42, 43: Introduction | * Human biospecimens refers to tissue, blood, urine, sputum, cells, or other biological material obtained from a person—but does not include micro-organisms.
* Research that involves human embryos, gametes, and stem cell lines is separately governed by the Research Involving Human Embryos Act 2002 and the Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (2017)
* Nobody should feel obliged to participate in research that involves human biospecimens
 | * researchers who utilize human biospecimens such as human tissue, blood, urine, cells, or sputum
 |  High |
| Pages 43-44: Recruitment or the acquisition andcollection of human biospecimens. | * Human biospecimens maybe donated voluntarily, extracted for clinical purposes, or collected after death
* Individuals who collect the biospecimens must be suitably qualified and experienced
* Biospecimens should be collected after death only if the person had agreed before they died or the authorized person consents after the death
* Biospecimens can be obtained from clinical pathology services only if the donor is not identified or consent has been waived
* If the biospecimen was imported from another nation, researcher need to ensure the procedure complied with relevant Australian legislation; otherwise, they should not use the biospecimen \*
 | * researchers who utilize human biospecimens such as human tissue, blood, urine, cells, or sputum
 |  High |
| Pages 44-45: Consent | * Before consent is sought, participants must receive information on how the biospecimens will be used, stored, and discarded, whether the biospecimens are identifiable and can be withdrawn, how health implications of the biospecimens will be communicated, and the financial implications of these biospecimens, such as commercial applications.
 | * researchers who utilize human biospecimens such as human tissue, blood, urine, cells, or sputum
 |  High |
| Page 45: Use of stored biospecimens | * If participants had not consented to the use of their biospecimens, researchers should not use these biospecimens unless a waiver seems appropriate—such as if the donors would most likely have consented if granted the opportunity.
 | * researchers who utilize human biospecimens such as human tissue, blood, urine, cells, or sputum
 |  High |
| Page 46: Communication of findings to participants | * If the biospecimens might reveal information that is relevant to the health of participants—or their relatives—researchers must develop a plan of how they will disclose or not disclose this information

This plan should consider * whether this disclosure is helpful—such as whether a suitable intervention is available
* how the participants, relatives, or communities will be contacted—and whether these individuals can choose whether they want this information
* the extent to which this information is valid rather than susceptible to error
 | * researchers who utilize human biospecimens— such as human tissue, blood, urine, cells, or sputum—and could generate information about the health of participants, their relatives, or their communities
 |  High |

**Chapter 3.3: Genomic research**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 47-48: Introduction | * Research that uses data about genes can generate health and hereditary implications to the relatives and communities of participants—yet, in some instances, these relatives or communities might not want to be informed of these implications \*
* Such genomic research may include family studies, clinical research, population health research, and so on
* Such genomic research could uncover issues—such as show a predisposition in participants of a particular disease—and could thus affect their employment prospects or access to services, culminating in discrimination or stigma \*
* To diminish risks, researchers should confine the research to genes that are relevant to the research questions
 | * researchers who conduct genomic research—in which they collect data about genes
 |  High |
| Page 48. Recruitment | * Sometimes, researchers also want to obtain information from the family members of participants; in these instances, the participants, not the researchers, should usually contact the family members
* If researchers are interested in collecting genomic information from particular communities, they should consult with relevant representatives of these communities
 | * researchers who conduct genomic research—in which they collect data about genes
 |  High |
| Pages 49-50 | To develop a procedure to obtain consent, researchers should consider* which information will be deliberately excluded from the research
* how will findings be communicated to participants, if at all
* the implications of this information to participants and their families or communities—such as whether insurance premiums or employment prospects might be affected
* the likelihood that participants could be re-identified
* Researchers should be aware the implications of genomic information could change over time, as scientific advances unfold \*
* Consent may be waived if genomic data or information had been de-identified or if prior consent is consistent with the scope of this research
* An opt-out approach should not be used in genomic research
* Sometimes, genomic research entails collection of family history, even when the family are unaware of this research. Researchers should document who provided this family history—recognising this information may not be complete
* Participants may not always want to receive the results of this research; if the communication of these results is mandatory, this condition should be specified during the consent procedure
 | * researchers who conduct genomic research—in which they collect data about genes
 |  High |
| Page 50: Data collection and management | * Researchers should recognize that, if they uncover a rare genetic disorder or mutation, the data may be identifiable—unless procedures are implemented to prevent identification
* Sometimes, researchers receive enough information to re-identify some material or information; they should refrain from re-identifying material or information as well as refrain from diminishing the privacy of participants
* Statutory or contractual duties may oblige participants to disclose the results of genetic tests or analysis to insurance companies or other third parties; participants should be advised of this possibility \*
* The storage of genomic information and bio-specimens should comply with the governance policies of the relevant biobank
 | * researchers who conduct genomic research—in which they collect data about genes
 |  High |
| Page 51-52: Communication of findings to participants | * Plans to relay the information to participants should include access to clinical services or genetic counselling
* These clinical services, in concert with the research team, should discuss which information should be relayed to participants—and comply with relevant guidelines such as the National Association of Testing Authorities
* Researchers are not expected to relay raw genomic data to participants
* If results could be relevant to relatives, the clinician of participants, or other appropriate clinical services, should discuss with participants the suitability of conveying these findings to relatives
 | * researchers who conduct genomic research—in which they collect data about genes
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| Pages 53-55: A plan for the potential return of findings to participants | * A plan on how researchers will disclose or not disclose genomic information to participants or relatives must be approved by the ethics committee
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**Chapter 3.4: Animal-to-human xenotransplanation**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 56-60: Introduction | * Xeno-transplantation is the transplantation, infusion, or implantation of live cells, tissues, or organs from another species
* Research that uses xeno-transplantation raises several ethical issues, such as the potential risk of disease transmission—from animals, to participants and then from participants to other people, such as close contacts
* Such research may entail lifelong monitoring of participants and close contacts
* Because the animal material cannot always be removed, consent cannot always be withdrawn
* The risks of xeno-transplantation are often unknown and can be potentially catastrophic.
* The use of animals must comply with the “Australian code for the care and use of animals for scientific purposes”
* The ethics committee needs to ensure that appropriate expertise is utilized to assess the research
* Researchers should develop a list of close contacts—people who may be affected by the research because they interact frequently with a participant. The definition of close contact will depend on the specific risks of this research
* Researchers need to consider all possible measures to diminish risk, such as specific pathogen-free herds or genetically modified animals—and develop a detailed plan on how to monitor and manage these risks.
* Risk also depends on the duration over which immunosuppression is warranted as well as the likelihood that participants will comply with the treatment regime or cope with complications.
* To obtain consent, researchers need to inform participants that risks may be unknown, that alternative treatments might be available, that close contacts might also be at risk, and the strategies to monitor and manage risks.
 | * researchers who conduct xeno-transplantation
 |  High |

**Chapter 4.1: Women who are pregnant and the human foetus**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 61-64 | * The wellbeing of pregnant women and the foetus—the developing human, anytime from fertilization to delivery—should be prioritized over the research
* Researchers need to consider how research on pregnant women could affect the foetus after birth as well
* Researchers should help pregnant women access counselling about these decisions—and involve other people, such as partners, who might be affected by these decisions
* Information and activities that relate to research should be separated from information and activities that relate to clinical care \*
* Whenever possible, researchers should monitor signs of distress in the foetus and cease research when applicable
* The possibility of contributing foetal tissue should not be raised before the decision to terminate has been reached \*
* Whenever possible, a researcher who is also the treating clinician should arrange someone else to seek consent \*
* Trade in human foetal tissue is prohibited.
* If pregnancy is terminated, researchers should not ask the woman to be involved in research if this request could damage her emotional wellbeing
* While seeking consent, the woman should be informed of potential commercial application of the research, including the development of cell lines, but that she will not be entitled to a share of the profits
* A foetus delivered alive must be treated as a child, with due care
 | * researchers who conduct research with pregnant women, human foetuses, or foetal tissue—unless the research revolves around gametes, embryos, or assisted reproductive treatments
 |  High |

**Chapter 4.2: Children and young people**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 65-67 | * When researchers conduct research with people under 18, several ethical issues might transpire—such as whether children understand the research well enough to consent, the prospect that children will feel obliged to participate, and the possibility that children and their parents will experience conflicting interests
* Even very young children may understand some of the relevant information about the research—and thus could be engaged in a discussion to determine consent
* Some children may understand all the relevant information about the research—but still may not be mature enough to reach decisions that align to their future interests \*
* Whether children are mature enough to reach these decisions depends on many considerations—and cannot be attached to a specific age \*
* Researchers should specify how they will gauge the degree to which the child is vulnerable or able to consent
* If the research revolves around education, discussions should be convened with the school community as well
* Children who are not mature enough to consent should be involved in research only if the research is relevant to the health and wellbeing of children; otherwise, researchers should recruit adults instead \*
* If the children are not mature enough to consent, at least one parent or guardian should consent instead; if the risks are more pronounced, both parents should consent \*
* Children may consent themselves—but only if they are mature enough, if the risk is low or negligible, and the research benefits the category of children to which this participant belongs
* Sometimes, seeking consent from parents is not possible because such consent might not be in the best interest of the child \*
* Sometimes, schools can organize standing parental consent—in which they consent to various kinds of research across a timeframe, such as one year.
* Schools can organize this consent provided the research entails anonymous surveys or overt observation of classrooms—and benefits the children
 | * researchers who conduct research with participants younger than 18
 |  High |

**Chapter 4.3: People in dependent or unequal relationships**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 68-69 | * Sometimes, the researchers have developed pre-existing relationships with potential participants. They may be managers, teachers, or service providers of these participants.
* In these instances, potential participants might feel obliged to participate, called implicit coercion
* If this arrangement is unavoidable, other measures should be considered to prevent implicit coercion: For example, researchers might organize a participant advocate or arrange someone else to obtain consent
* Some members of vulnerable communities, such as students, could be subjected to excessive research, compromising the principle of justice
* Researchers must initiate measures to guarantee that people who agree or refuse to participate are not unfairly disadvantaged
* Nevertheless, researchers also need to ensure these people do not overestimate the benefits of participation, such as presume they will be favoured in some way \*
* Confidentiality may demand more effort when the researchers and participants share a workplace or setting
 | * researchers who may conduct research with participants in which they have already established a relationship
 |  High |

**Chapter 4.4: People highly dependent on medical care who may be unable to consent**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 70-72 | * When people experience serious risks to their lives or wellbeing—such as while they are treated in emergency, intensive, or palliative care—they may become very dependent on medical interventions or treatments
* Many ethical issues arise; for example, they might not be in a state to comprehend the research and refuse consent
* Yet if researchers refrain from conducting research with these individuals, because of the risks, they may not be exposed to the benefits of research either
* The risks and benefits of neonatal intensive care research need to be considered carefully by relevant experts—because the impact of research can be enduring and delayed
* A risk in terminal care research is that participants might overestimate the potential benefits of this research—and researchers must thus manage these expectations carefully. The research should not impinge on the time these individuals spend with family members
* If their verbal or written communication is impaired, researchers need to uncover other ways to impair information
* Individuals who are unconscious should be exposed to only minimally invasive research
* If individuals are not in a state to consent, a guardian or person authorized by law can provide consent instead.
* Researchers need to introduce measures to ensure that feelings of distress—or the dependency of participants and families on the medical services—have not affected the decision to consent \*
* The person who seeks consent should not, if possible, be the treating health professional
* If consent cannot be arranged, the research might proceed, provided the intervention is likely to be better than standard care, the risks are minimal, and the relevant individuals would most likely have provided consent; the relevant individuals, such as guardians, should be contacted as soon as possible—and the option of withdrawal should be communicated \*
 | * Researchers who conduct research on participants who are very dependent on medica care
 |  High |

**Chapter 4.5: People with a cognitive impairment, intellectual disability, or mental illness**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 73-74 | * If participants exhibit cognitive impairment, an intellectual disability, or mental illness, several ethical issues might transpire. Informed consent might be impaired.
* These individuals may also be more likely to experience distress during the research—and hence researchers need to clarify how they will manage or prevent these emotions \*
* If these individuals are unable to consent, consent could be sought from a legal guardian or legally authorized entity
* If the impairment, disability, or illness fluctuates, researchers should seek consent at a time in which the condition does not interfere with consent—even if a legal guardian or authority has already consented
* While seeking consent, researchers might need to discuss with participants how they should act if the capacity to provide consent in the future subsides \*
* Researchers need to inform the ethics committee how they will decide whether the individuals can consent
 | * researchers who may conduct research with participants who exhibit cognitive impairment, an intellectual disability, or mental illness
 |  High |

**Chapter 4.6: People involved in legal activities**

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| Section | Main contents | This section is targeted at… | Urgency |
| Pages 75-76 | * Some research may discover past or planned illegal activity
* In these instances, the ethical and legal issues primarily revolve around what researchers might be obliged to disclose—because of statutory obligations or legal orders
* Furthermore, the discovery of illegal activity could increases risks to participants or even researchers
* Research should not be conducted with the explicit aim to discover illegal activity—unless this illegal activity affects the discharge of a public responsibility or the suitability to hold public office
* Measures to limit connections between names and data, such as pseudonyms, are especially relevant to research that could reveal illegal activity
* Researchers should ensure participants who are subject to criminal justice processes are aware the research could discover illegal activity—and do not overestimate the potential benefits of participation
* Researchers need to inform participants of the prospect that illegal activity could be discovered—as well as limits to confidentiality because of statutory obligations or legal orders \*
 | * researchers who conduct research with participants who may be involved with illegal activity
 |  High |

**Chapter 4.7: Aboriginal and Torres Strait Islander people**

If your research is intended to revolve around Aboriginal and Torres Strait Islander peoples or communities, you should first read “Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018”.

**Chapter 4.8: People in other countries**

|  |  |  |  |
| --- | --- | --- | --- |
| Section | Main contents | This section is targeted at… | Urgency |
| Pages 80-82 | * When Australian researchers conduct research in another nation, they may need to comply with beliefs, customs, and values that diverge from the National Statement. Indeed, the legal, ethical, and regulatory frameworks of other nations might conflict with the National Statement
* In these instances, the researchers must still be guided by the National Statement but also consult communities in these nations to respect, protect, and accommodate overseas participants
* Various bodies, such as funding agencies, might oblige researchers to comply with the ethical guidelines of other institutions or nations; regardless, no participant should be accorded less respect and protection that stipulated by the National Statement
* Researchers should clarify how they will ensure this respect and protection—such as how they might access the expertise of other individuals
* Researchers need to accommodate not only the laws of other nations but also cultural, political, and social issues, including issues that could jeopardize the wellbeing of participants
* Overseas participants should be able to access a contact in their nation to field questions and complaints—someone independent of the researcher
 | * researchers who conduct research with overseas participants
 |  High |

**Chapters 5.1 to 5.7**

These chapters primarily describe the roles and responsibilities of ethics committees and institutions, such as how to review ethics applications, monitor projects, and manage complaints as well as the composition of ethics committees. Nevertheless, a few principles for these chapters are relevant to researchers. For example, one responsibility of ethics committees is to minimize duplication. To illustrate, if two universities collaborate on a research project, only one ethics committee should review the ethics application in detail.