PUBLIC CONSULTATION ON SECTION 3 (CHAPTERS 3.1 & 3.5), GLOSSARY AND REVISIONS TO SECTION 5

NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH, 2007

November 2016

WORKING TO BUILD A HEALTHY AUSTRALIA
An invitation to make a submission

Draft Chapters in Section 3 and Section 5 for inclusion in the National Statement on Ethical Conduct in Human Research (2007)

The National Health and Medical Research Council (NHMRC) is proposing to include new and revised chapters in Section 3 and amendments to Section 5 of the National Statement on Ethical Conduct in Human Research (2007) (the National Statement). Developed by the Australian Health Ethics Committee (AHEC), the draft chapters provide advice for both researchers and Human Research Ethics Committees (HRECs) addressing ethical considerations in the design, development, review and conduct of research (Chapter 3.1) and ethical considerations specific to genomic research (Chapter 3.5). New introductory language for Section 3 has also been developed. The changes to Chapters 5.1, 5.2 and 5.5 (outlining institutional and researcher responsibilities) that are proposed follow from and are a consequence of the changes to Section 3.

I am pleased to release the draft guidance for public consultation, and welcome feedback from interested parties, in particular whether the draft chapters:

- provide sufficient guidance to address the key ethical issues in relation to the design, development, review and conduct of research; and
- are presented and written in a manner that is appropriate for the target audience (researchers, HRECs).

The proposed drafts are accompanied by explanatory material to provide clarity regarding the changes in structure and content that have been introduced to Section 3 and the rationale for the amendments to Section 5.

Under Section 13 of the National Health and Medical Research Council Act 1992, NHMRC is required to undertake public consultation prior to finalising its human research guidelines. NHMRC is keen to ensure that the Australian community has the best opportunity to participate in developing guidance on matters of health ethics, and now seeks your comments on the proposed changes to the National Statement. I encourage you to bring this public consultation to the attention of anyone whom you believe would be interested. Submissions received as part of the public consultation will be considered in the final revisions to the chapters.

We look forward to receiving your comments.

Yours sincerely

Professor Anne Kelso AO
Chief Executive Officer
1 November 2016
Public consultation on Section 3 and Section 5 – Explanatory material

What is the scope of the proposed changes?

The *National Statement on Ethical Conduct in Human Research (2007)* was last completely revised over the period 2004 to 2007. At the completion of that revision, it was decided that a ‘rolling review’ would be undertaken to keep the document up-to-date. This means that instead of undertaking a full review of the National Statement at one time, sections of the National Statement would be updated as required.

An online survey developed by the NHMRC, with input from Universities Australia and Australian Research Council was conducted in late 2013 and early 2014. The survey identified Sections 3, 4 and 5 of the National Statement as the main priority sections to review. Section 3 was identified as the highest priority for review. Revision of Section 3 has been conducted by two expert committees, one each for Chapter 3.1 and Chapter 3.5, respectively.

The proposed changes to the National Statement include:

- a new title and introductory language for Section 3
- a new chapter, Chapter 3.1, that focuses on the elements of human research and which both merges and expands upon guidance currently included in Chapters 3.1, 3.2 and 3.3
- a revision of Chapter 3.5, addressing ethical considerations in human genomic research (formerly entitled ‘Human Genetics’)
- consequential changes to Section 5 that are necessary as a result of the changes to Section 3
- the addition of terms to the Glossary.

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<thead>
<tr>
<th>CURRENT CONTENT</th>
<th>NEW CONTENT</th>
<th>COMMENT</th>
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<tr>
<td>Introduction to Section 3: Ethical considerations specific to research methods or fields</td>
<td>Introduction to Section 3: Ethical considerations in the design, development, review and conduct of research</td>
<td>The introduction has been revised to introduce and explain the new themes and structure for the section.</td>
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<tr>
<td>Chapter 3.1: Qualitative methods</td>
<td>Chapter 3.1: The elements of research</td>
<td>Chapters 3.1, 3.2 and 3.3 have been combined into a single chapter with additional material and the relocation of some material from Chapter 3.3 into Section 5.</td>
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<tr>
<td>Chapter 3.2: Databanks</td>
<td>No Change</td>
<td>As this chapter was reviewed in 2014, it has not been included in this review and no changes to it are being recommended.</td>
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<td>Chapter 3.3: Interventions, etc.</td>
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<td>Chapter 3.4: Human Biospecimens</td>
<td>No Change</td>
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<td>Chapter 3.5: Human genetics</td>
<td>Chapter 3.5: Genomic Research</td>
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<td>Chapter 5.1: Institutional responsibilities</td>
<td>Minor additions and modifications</td>
<td>Changes have been introduced to (a) accommodate material from Chapter 3.3 (b) reflect current standards regarding safety monitoring and (c) adjust numbering and cross-references.</td>
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<tr>
<td>Chapter 5.2: Responsibilities of HRECs … and researchers</td>
<td>Minor additions and modifications</td>
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<td>Significant modifications</td>
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<tr>
<td>Glossary</td>
<td>New glossary terms</td>
<td>The new glossary terms reflect the new content of Chapters 3.1 and 3.5.</td>
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What is the rationale for the proposed changes?

The revised section 3.1 reflects a new structure based around the concept of ‘elements of research’ and provides guidance that is intended to apply to all types of human research, rather than organising the guidance under categories, types or methods of research, as was previously provided. However, it was also determined that specific areas of advice in other chapters in Section 3, namely chapters on human biospecimens in laboratory based research (current Chapter 3.4) and on human genetics (current Chapter 3.5), should be retained.

The revised chapter on human genetics now encompasses ‘genomic research’ and has been revised to better reflect current developments in the field, including expanded advice on issues such as the management and potential return of findings from this research. It also includes a flow chart for researchers to use as they consider these issues. The current Chapter 3.4 dealing with human biospecimens, revised in 2014, has not been revised as a component of the current work, and is not included in the materials for this public consultation, but may undergo formatting changes to be compatible with the final revisions to other chapters in Section 3.

The proposed changes to Section 3 resulted in the removal of a number of provisions related, in particular, to clinical trials that were determined to be more appropriately located in Section 5, specifically Chapters 5.1, 5.2 and 5.5. Some of these provisions have been slightly modified to reflect guidance on safety monitoring and reporting that is under concurrent development by NHMRC.

What is the impact of the proposed changes on the National Statement as a whole?

The proposed changes to Section 3 should be read in the context of the document as a whole, as reference to guidance in other sections of the National Statement is necessary for a comprehensive understanding of the guidance provided in the revised chapters in Section 3 of the National Statement. To inform your review and comment on the proposed changes, please refer to the current National Statement, located at http://www.nhmrc.gov.au/guidelines-publications/e72.

A notable change in Section 3 is the integration of some of the material in current Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations into the new Chapter 3.1 and the relocation of other material from Chapter 3.3 into Section 5. You may wish to consider whether the guidance related to interventional research, particularly clinical trials of unapproved therapeutic substances, devices or biologicals, is sufficient.

It has also been noted that the language used in Element 4: Data Collection and Management of Chapter 3.1 related to data identifiability, specifically, the terms ‘individually identifiable data’, ‘re-identifiable data’ and ‘non-identifiable data’, although consistent with Chapter 3.2 of the current National Statement, contrast with the categories of information used in privacy legislation, i.e. ‘identified data’, ‘potentially identifiable data’ and ‘de-identified data’. You may wish to consider whether it is advisable for the National Statement to use language that is consistent with privacy legislation.
Introduction to Section 3 and Section 3.1
National Statement Section 3

Ethical considerations in the design, development, review and conduct of research

Introduction

The aim of this section is to identify ethical considerations that are relevant to the way that research is designed, reviewed and conducted and to provide guidance regarding appropriate actions that may be taken to address these issues. This material should be read in conjunction with the Preamble (Purpose, scope and limits, p.6) and Section 2 (Themes in research ethics: risk and benefit, consent, pp 12-21).

This section aims to be compatible with and relevant for many different ways of doing human research. It requires those involved in the conduct and approval of human research to consider and reflect on the nature of the individual research project, in particular:

- how the research question/theme is identified or developed
- the alignment between the research aims and methods
- how the researchers and the participants will engage with one another
- how the research data are to be collected, stored, and used
- how the results or outcomes will be communicated, and
- what will happen to the data after the project is completed.

The guidance in this section is deliberately ‘high level’. This means that, rather than issue a comprehensive list of instructions for different research fields or methodologies, we have identified common ethical issues that arise in the various phases of research. It is up to each researcher and HREC to apply the guidance to their own project, taking account of the four principles of research merit and validity, justice, beneficence and respect.

The guidance in Chapter 3.1 is broadly applicable to all fields of research, including those types of research for which additional specific guidance is provided in Chapters 3.2, 3.3 and 3.4. Through a consideration of what the researcher/s propose to do, with whom and how, this guidance facilitates consideration of the risks and benefits of the research and the level of ethical oversight required.

Chapter 3.1 is designed around seven elements that are common to most or all forms of research. The chapter starts with considering the ethical issues associated with developing the research scope, aims, themes, questions and methods, and ends with ethical considerations that pertain after the project comes to an end.

The elements are:
Element 1 – Research Scope, Aims, Themes, Questions and Methods
Element 2 – Recruitment
Element 3 – Consent
Element 4 – Data Collection and Management
Element 5 – Communication of Research Findings or Results
Element 6 – Dissemination of Research Outputs and Outcomes
Element 7 – After the Project
Researchers who are designing a research project should read all of Chapter 3.1, noting which parts of the guidance are relevant for their project. In addition, if research involves biospecimens, genomics or xenotransplantation, they should also consult the specific chapters on these topics.

Members of HRECs reviewing research can easily refer to any element about which they have queries when reviewing a project. For example, if concerned about recruitment for an educational interventional trial, relevant information can be found in Element 2 on recruitment.

Each subsequent chapter in this section (Chapters, 3.2, 3.3 and 3.4) provides guidance on particular ethical considerations that may apply to specific types of research or with respect to specific research methods, where these raise issues that are additional to material covered in chapter 3.1. Specific guidance is provided for:

- Use of human biospecimens in laboratory based research
- Genomic research
- Xenotransplantation research.

Researchers planning to do any type of research involving Aboriginal and Torres Strait Islander peoples must consult and follow the advice in the most contemporary versions of *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Research 2003* and *Keeping Research on Track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics 2005* as well as the *Guidelines for Ethical Research in Australian Indigenous Studies* (GERAIS) produced by the Australian Institute of Aboriginal and Torres Strait Islander Studies. These guidelines embody the best standards of ethical research and human rights and seek to ensure that research with and about Aboriginal and Torres Strait Islander peoples follows a process of meaningful engagement and reciprocity between the researcher and the individuals and/or communities involved in the research.

Researchers should also consult the most contemporary version of NHMRC’s *Statement on Consumer and Community Participation in Health and Medical Research*. 
CHAPTER 3.1: THE ELEMENTS OF RESEARCH

Introduction

The design of any human research project must adhere to the core ethical principles described in Section 1 of this National Statement. These must be considered from the earliest conception of a project and guide its design.

Human research can involve a wide range of methods and practices: it can be qualitative, quantitative or mixed; interventional, experimental or observational in nature; and involve various degrees of collaboration between researchers and participants. Each research project is shaped by the field to which the research question relates, the research question itself, the desired outcome, and the context in which it is conducted.

Effective research ethics review will have an understanding of, or will have access to expert advice about, relevant methods or areas of practice. Reviewers must apply expectations or requirements that are relevant to the areas of practice or methods used in projects they review; and acquaint themselves with methods or areas of practice with which they are unfamiliar or that are novel.

A range of relationships between participants and researchers may develop as a result of the duration and nature of the research interaction. Some methodological approaches require careful boundaries to be maintained between researchers and research participants; while other research fields require data collection methods that involve the development of close personal relationships with participants, or degrees of collaboration that blur the lines between researcher and participant (e.g. co-researchers in action research).

Researchers should reflect on the impact that they may have on the participants and vice versa, and as far as possible should describe in the research proposal any anticipated impact of this nature. Where the impact threatens to compromise their role or their professionalism, researchers must consider whether to modify those relationships, or to modify or discontinue the research.

Where a researcher has other professional skills (for example, counseling or clinical care) that become relevant to the relationship with a participant, the researcher needs to decide, when continuing the research, whether:

(a) it is ethically acceptable to exercise those skills; or
(b) to refer that participant to another professional.

Researchers have a duty to inform participants whenever they are acting in a professional rather than a research role.

Research may involve emotional and other risks to both participant and researcher. There should be clear protocols for dealing with distress that might be experienced by participants during the process of data collection or conduct of research procedures. Predicting what topics are likely to lead to distress will not always be easy. Researchers should have sufficient training to help them in making such predictions. Refer to Chapter 2.1 for a further discussion about the identification and handling of risk in research.
This chapter discusses the manner in which these core principles should be reflected in the elements of research project design. The chapter should be considered as a whole; however, the order in which these elements are discussed does not imply a hierarchy or a sequence in which they are to be considered, or that all of these elements will have equal relevance in every design. The elements are:

Element 1: Research Scope, Aims, Themes, Questions and Methods

Element 2: Recruitment

Element 3: Consent

Element 4: Data Collection and Management

Element 5: Communication of Research Findings or Results

Element 6: Dissemination of Research Outputs and Outcomes

Element 7: After the Project
Guidelines

Element 1: Research Scope, Aims, Themes, Questions and Methods

In designing a human research project, researchers must consider how their project will meet the ethical requirement that research has merit, as described in paragraph 1.1 of the National Statement. This Element of Chapter 3.1 offers advice and guidance about meeting this obligation.

Key questions include:
- What is the research theme or question that this project is designed to explore?
- Why is the exploration of this theme or answer to this question worth pursuing?
- How will the planned methods explore the theme or answer the question?

3.1.1 In an application for review of their research, researchers should determine and state in plain language:
(a) the research question or questions that the project is intended to explore;
(b) the potential benefit of exploring the question or questions including:
   (i) to whom that potential benefit is likely to flow, and
   (ii) whether that benefit is a contribution to knowledge or understanding, improved social or individual wellbeing, or the skill and expertise of researchers;
(c) the basis for that potential benefit as described in either relevant literature or a review of prior research unless, due to the novelty of the question, there is scarce literature or prior research;
(d) how the design of the project will maintain respect for the participants;
(e) that the participants to be recruited are appropriate and adequate to explore the research question or questions;
(f) where relevant, that the research meets the requirements of any relevant regulations or guidelines authorised by law (such as those related to privacy and reporting requirements for disclosure of child abuse); and
(g) whether or not the project has been reviewed by a formally constituted academic, scientific or professional review process.

3.1.2 For research conducted in the context of the provision of health care, researchers should additionally determine and state:
(a) whether the project involves the systematic investigation of the safety and efficacy of an intervention;
(b) whether, if an innovative intervention is being introduced, it is likely or possible that the innovation will be of therapeutic benefit;
(c) whether there is a realistic possibility that the innovative intervention being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burdens, costs and risks;
(d) where patient care is combined with intent to contribute to knowledge, that any risks of participation should be justified by potential benefits to which the participants attach

1 A notable change in Section 3 is the integration of some of the material in current Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations into the new Chapter 3.1 and the relocation of other material from Chapter 3.3 into Section 5. You may wish to consider whether the guidance related to interventional research, particularly clinical trials of unapproved therapeutic substances, devices or biologicals, is sufficient.
significance. The prospect of benefit from research participation should not be exaggerated, either to justify to an HREC a higher risk than that involved in the participant’s current treatment or to persuade a participant to accept that higher risk;

(e) whether the research is without likely benefit to participants, or whether the benefits or risks cannot be accurately estimated in advance. For such research to be ethically acceptable, the known risk to participants must be lower than for research in which there are likely benefits; and

(f) when research involves the use of a placebo alone or the incorporation of a non-treatment control group, the use of the placebo or control group may be considered where there is genuine uncertainty as to whether currently available treatments have a net clinical benefit; however, the research is ethically unacceptable in a controlled clinical trial where

(i) other available treatment has already been clearly shown to be effective; and
(ii) there is known risk of significant harm in the absence of treatment.

3.1.3 For clinical trial research, researchers must register the project in a publicly accessible register before the recruitment of the first participant.

3.1.4 The rigour and disciplinary merit of research should be assessed by criteria and standards relevant to the research field/s and methodology/ies, such as

(a) the objectives and conceptual basis of the research;

(b) the quality and credibility of data collection and analysis; and

(c) the levels of validity and reliability that are necessary to be able to generalise the findings or results.

3.1.5 In their assessment of research quality, reviewers must recognise that thematic and other forms of generalisability may be more relevant than statistical generalisability.

3.1.6 Reviewers should be aware that some research designs will be informed and shaped by the experience, insights and/or needs of participants, including any co-researchers. Such designs can be a valid and powerful way to collect qualitative information and to inform practice.

3.1.7 Where the total project cannot be described in advance because it will be realised in successive stages whose detail and design will be informed by preceding stages, researchers should provide an indicative description of the stages that are foreseen and how it is intended to seek approval for each of these.

3.1.8 To facilitate the consideration of a project with regard to the ethical principles of merit and integrity, researchers should confirm and reviewers should be satisfied that:

(a) a plan is in place to ensure that resources are sufficient to conduct and complete the research as designed; and

(b) the facilities, expertise and experience available are appropriately allocated and sufficient for the research to be completed safely.

3.1.9 Researchers should provide assurance that any proposed payment in money or kind, whether to institutions, researchers or participants, will not adversely influence the design, conduct, findings or publication of the research.
Element 2: Recruitment

When research will involve the direct participation of people (e.g. testing, surveys, interviews, focus groups, observation and health or behavioural interventions) the recruitment phase of a project can be fundamental to the success of the research. Recruitment can raise ethical challenges for the design and conduct of projects. Depending upon the design of a project this element can include such matters as: identifying individuals as potential participants, making contact between the research team and potential participants, screening or exclusion of some individuals, and preparing to seek consent from the potential participants. A single project may employ more than one recruitment strategy, especially where discrete cohorts are required to meet the objectives of the research. For some research designs, the recruitment and consent strategies can occur concurrently, whilst, for others, they can be separate. It is essential that the selected recruitment strategies adhere to the ethical principles of justice and respect.

Key questions include:

- Who will be recruited?
- How will participants be identified and recruited?
- Will the potential participant pool be screened?
- What is the impact of the relationship between researchers and potential participants on recruitment?
- How will the recruitment strategy facilitate obtaining the consent of participants?
- How will the recruitment strategy ensure participants can make an informed decision about participation?
- Are there any risks associated with the recruitment strategy?

3.1.10 The potential participant pool for a project should align with the objectives and theoretical basis of the research.

3.1.11 Research proposals should clearly describe the recruitment strategy and criteria for selecting participants.

3.1.12 The selection and conduct of a recruitment strategy for a project should be relevant to the research methodology, topic/subject matter, the potential participant pool and the context.

3.1.13 The inclusion/exclusion criteria for the potential participant pool for a project must be fair and justifiable. The exclusion of some groups may amount to unfair discrimination, and/or exclude individuals and groups from the potential benefits of research. Researchers should consider the degree to which including/excluding groups may limit (or compromise) the value of the results of a project, with consequent impact on the merit of the project.

3.1.14 The design and conduct of a recruitment strategy must be respectful of potential participants, facilitate voluntary participation, and have due regard for their welfare, culture, traditions and beliefs.

3.1.15 Researchers and research ethics reviewers should consider the degree to which potential participant populations might be over-researched or may require special consideration or protection and the degree to which the flow of benefits to that population (or to individual participants) justify the burdens. Equally, people should not be denied the opportunity to obtain
the potential benefits of research or exercise self-determination solely because they are a member of a population that might be over-researched or may require special consideration or protection.

3.1.16 In developing and implementing their recruitment strategy, researchers should consider:
   (a) the potential for coercion/exploitation;
   (b) any risks related to recruitment (see NS Chapter 2.1) and how the pattern of recruitment might be structured to mitigate any risks to participants;
   (c) any privacy matters relating to the recruitment of participants;
   (d) the potential impact of existing relationships on recruitment (including, but not limited to, hierarchical relationships such as teacher and student, manager and employee, supervisor and team member, treating health care professional and patient that may generate an unequal or dependent relationship);
   (e) the potential impact of participation on existing relationships;
   (f) whether participants will be recruited by co-researchers unfamiliar with the guidance provided by this National Statement; and
   (g) whether the research requires community engagement or research agreements to be in place prior to individual recruitment.

3.1.17 In clinical trials, researchers must ensure that participants understand whether there is intended to be any therapeutic benefit to them from the trial and whether access to the interventional therapy is available only through participation in the trial.

3.1.18 When a project relates to some form of health intervention or treatment, researchers must make it clear to potential participants whether it is innovative and/or experimental.

3.1.19 In clinical research, where patient care is combined with research, researchers and reviewers should carefully weigh the following matters:
   (a) the seriousness of the condition being treated; and
   (b) the risks that are additional to those inherent in the disease or condition and its standard management.

3.1.20 Researchers should consider how the potential participants will experience the recruitment process.

3.1.21 Researchers should consider the potential impact of the recruitment strategy upon the consent process (e.g. the degree to which the recruitment strategy might undermine the voluntary nature of the consent of individual potential participants).

3.1.22 Reviewers should consider the degree to which any payment in money or incentives of any kind, whether to researchers or participants, could result in pressure on individuals to consent to participate (see paragraphs 2.2.10, and 2.2.11). This is especially important with respect to research that involves more than a low risk of harm.

3.1.23 Researchers should describe and justify their approach to potential participants (i.e. how do they find out about the possibility of participating in or opting out of the research). The level of detail that reviewers might require should be proportional to the foreseeable risks and appropriate to the methodology selected.
3.1.24 Researchers should provide the reviewers with drafts of recruitment materials (e.g. notices, flyers, advertisement, and social media posts) prior to use, which may or may not be concurrent with initial review of the research proposal.
Element 3: Consent

The selection of a consent strategy, approach and mechanism for a project must be appropriate for the potential participants, the research design, the topic and the context. The manner and process for obtaining consent must be respectful and have the objective of facilitating the valid consent of potential participants. Obtaining consent may be a component of broader processes of consultation, engagement and negotiation, particularly in the context of research involving Aboriginal and Torres Strait Islander Peoples.

Key questions include:
- What strategy(ies), approach(es) and mechanism(s) for obtaining consent, or alternatives to consent are appropriate for the specific project?
- Does the nature of the design, the participants or the context necessitate the use of more than one strategy, mechanism or approach?
- Do the proposed strategy(ies), approach(es) and mechanism(s) satisfy the relevant requirements of Chapters 2.2 and 2.3 of this National Statement?
- Are there any project-specific matters that warrant specific attention (e.g. whether the research could generate results of significance to participants, whether the data will be added to an open access repository or whether the data or materials will be used for any other purpose)?

3.1.25 The approach taken to consent of participants is a critical component of the ethical design and conduct of human research. Chapters 2.2 and 2.3 provide essential guidance for the selection and framing of a strategy for consent or alternatives to consent, such as an opt-out approach or waiver of the requirement for consent. Researchers should ensure that any proposed consent strategy, approach and mechanism:
(a) provides all of the required information and assurances as set out in those chapters, as relevant to the proposed research;
(b) is relevant to the objectives of the proposed research; and
(c) uses tools and language that are appropriate, respectful and relevant to the research design, topic, potential participant pool and context, including relevant cultural sensibilities.

3.1.26 Researchers and reviewers should recognise that research that involves multiple methods or different potential participant pools may require more than one consent strategy and that some research (particularly some qualitative designs) may require consent to be revisited and renegotiated over time.

3.1.27 Researchers should ensure that the consent strategy is clear as to whether third parties (including supervisors of participants) will know who has been approached about participating, who has been selected from the participant pool, and which individuals have chosen to participate. This information should be clearly represented to potential participants.

3.1.28 In circumstances where there may be significant risks if the participatory status of individuals becomes known, researchers should select a consent mechanism that masks the identity of participants.
3.1.29 When those who are recruiting participants will receive some form of payment per recruited individual, this must be disclosed to potential participants during the consent process.

3.1.30 The complexity of an information and consent document or other consent mechanism should be proportional to the project’s risks and ethical sensitivity. Specifically,
(a) written information should not be unduly long or complex, even for complex interventional research;
(b) the use of mechanisms such as the provision of tiered information should be considered; and
(c) adequate time should be allowed for prospective participants to read and take in what is proposed and for their questions and expression of concerns (See 2.2.2 – 2.2.6).

3.1.31 Where research may yield findings that are potentially significant for individuals, the consent strategy must clarify whether participants will be provided with these findings or whether individuals will have a choice about receiving the findings.

3.1.32 Researchers should advise participants whether they will be provided with a timely and appropriate summary of the outcomes of the research, whether in the form of a lay summary, a research manuscript or published paper or both.

3.1.33 For clinical trials or other interventional research conducted in a clinical setting, researchers should advise participants as to whether they will have continued access to the interventional therapy, treatment or information that they have received during the research, and with what limitations, if any.

3.1.34 For research that is not explicitly or primarily genomic, but involves a health intervention that may, during recruitment or data collection, generate information with hereditary implications, consent processes should be designed to take account of this potential (see Chapter 3.5: Genomic Research).

3.1.35 Researchers should describe to potential participants any limitations on/consequences of withdrawing consent, including with respect to data that has been collected without identifiers or where identifiers have been removed.

3.1.36 Researchers should disclose to potential participants whether, and under what circumstances, research results or information that has been collected may be reported to relevant authorities.

3.1.37 A witness to a participant’s consent is not a requirement of these guidelines, although these guidelines do not preclude the use of witnesses as required by bodies that authorise research.
Element 4: Data Collection and Management

This section includes ethical issues related to collection, generation, access, use, analysis, disclosure, storage, sharing and disposal of data.

Human research projects will incorporate one or more methods to collect, generate or access data so as to achieve the objectives of the research. Data may include ‘research materials’ such as human biospecimens, laboratory notes, digital information, survey responses, test results, or other objects containing personal information. Collection and management of the data and materials must be in accordance with the ethical principles discussed in Section 1 of this National Statement.

Research may involve access to large volumes of information not explicitly generated for research purposes. The size and accessibility of such sources make them attractive for some research designs, but use of this data raises complex privacy and consent questions. The increased ability to link data has greatly enhanced the contribution that collections of data can make to research, as it enables researchers to match individuals in different data sets without identifying the person. For example, in epidemiological research (concerned with the study of populations), information about individuals and groups may be collected so that features of groups of people can be investigated, even when these data were not originally collected for research purposes.

**Key questions include:**
- What data and research materials are required to achieve the objectives of the project?
- How will the data and research materials be collected, generated and/or accessed?
- How will the data and research materials be used and analysed?
- Will the data be disclosed or shared and, if so, with whom?
- How will the data and research materials be stored and disposed of?
- How will the collection and management of the data and materials adhere to the ethical principles in Section 1 of this National Statement?

Data are pieces of information, for example:
- what people say in interviews, focus groups, questionnaires/surveys, personal histories and biographies;
- images, audio recordings and other audio-visual information;
- records generated for administrative purposes (e.g. billing, service provision) or as required by legislation (e.g. disease notification);
- digital information generated directly by the population through their use of the internet
- information generated by analysis of existing identified personal information (clinical, social, observational or other);
- observations;
- results from experimental testing and investigations;
- information derived from human biospecimens such as blood, bone, muscle and urine.
Data identifiability

Data may be collected, stored or disclosed as:

- individually identifiable data, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual’s name, image, date of birth or address;
- re-identifiable data, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, unlocking the code or linking to other data sets that contain identifiers;
- non-identifiable data, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, such that no specific individual can be identified.

This National Statement does not use the term ‘de-identified data’, as its meaning is unclear: it may refer to a record that cannot be linked to an individual (‘non-identifiable’), or it may refer to a record for which the means still exist to re-identify the individual (‘re-identifiable’).²

3.1.38 When the term ‘de-identified data’ is used in project documentation, researchers and reviewers should establish which of the possible meanings is intended.

3.1.39 The identifiability of data may change during the life of a research project (e.g. data might initially be collected in an individually identified form, then coded for analysis and correlation to other collected data, and, finally, once all the data has been collected, the code key might be destroyed, rendering the data non-identifiable). Researchers should explain any such process to potential participants in terms of its impact on

(a) risk management;
(b) withdrawal of consent;
(c) communication of research findings and outcomes to participants; and
(d) the responsible storage of data.

3.1.40 Researchers and reviewers should recognize that identifiability of data is also conditioned by contextual factors, such as to whom the data is identifiable (e.g. it may be identifiable or re-identifiable to the person/s collecting the data, but non-identifiable to the person/s to whom the data is disclosed or shared for the purposes of research).

3.1.41 Where participants are potentially identifiable and the information that they provide may be sensitive, such as in research projects that focus on members of small communities, or key individuals, researchers should ensure that participants are not identifiable from the information they provide, unless they have agreed to be identified. This may require not only obscuring, but also sometimes changing identifying details, either in the data collection process or when presenting and publishing the research results.

² The language used in Element 4: Data Collection and Management of Chapter 3.1 related to data identifiability, specifically, the terms ‘individually identifiable data’ ‘re-identifiable data’ and ‘non-identifiable data’, although consistent with Chapter 3.2 of the current National Statement, contrast with the categories of information used in privacy legislation, i.e. ‘identified data’ ‘potentially identifiable data’ and ‘de-identified data’. You may wish to consider whether it is advisable for the National Statement to use language that is consistent with privacy legislation.
3.1.42 It should not be assumed that non-identifiability of data is ethically required. Some research populations (e.g. academics, activists and some public figures) are amongst those who may prefer to be identified rather than anonymised in the collection, use, and reporting of research data. Where participants choose to be identified, researchers and participants should collaboratively determine and agree upon whether all research data collected from them will be identifiable, or only certain components of the collected data.

3.1.43 Where research involves linkage of data sets, researchers should advise participants that use of identifiable data may be required to ensure that the linkage is accurate, but that, once linkage has been completed, identifiers will be removed from the data to be used in the research, unless consent has been obtained for the use of identifiable data in the research.

3.1.44 With advances in genomic knowledge and data linkage and the proliferation of biobanks, biospecimens and, in some cases, the data associated with them should always be regarded as, in principle, re-identifiable.

**Internet-derived data**

Research may involve access to and use of internet-derived data relating to individuals, including social media posts, tweets, self-generated ‘lifelogging’ data emitted from mobile phones and other ‘smart’ appliances and data generated through applications such as fitness monitoring devices and web-based games, gambling and dating. Such data may be public (or semi-public), but this does not automatically mean that individuals permit the use of this material for research.

3.1.45 For research using internet-derived data, researchers should make study designs readily available to persons to whom the data relates, including information about:
(a) the form in which the data will be stored (identifiable, re-identifiable, non-identifiable);
(b) the purposes for which the data will be used.

3.1.46 Unless a waiver of the requirement for consent is obtained, any research use of internet-derived data must be in accordance with the consent obtained from the person to whom the data relates.

3.1.47 Researchers should respect the context in which internet-derived data were posted and the privacy settings that apply.

3.1.48 Researchers should take account of any terms and conditions applicable to social media platforms when using data from these sources (e.g. Twitter) and other web-based communities that do not permit the removal of the name of the author of a post or any changes to the wording of a post.

**Data management**

3.1.49 Researchers should reach mutual agreements with collaborators regarding the ownership, storage location, right to access, right to analyse/use and right to produce research outputs based upon stored data/ biospecimens. Such an agreement need not necessarily be a contractual document, but should facilitate a clear resolution of these issues.
3.1.50 Researchers should accurately record data in a durable and appropriately referenced form that complies with the *Australian Code for the Responsible Conduct of Research*, established legislation, policies and guidelines.

3.1.51 When planning a project/databank, researchers should clearly describe how their research data will be stored, shared/disclosed and disposed of, and how that process conforms to the requirements for consent set out in paragraphs 2.2.14 to 2.2.18.

3.1.52 Unless otherwise authorized by an ethical review body, any sharing of data must adhere to the principle of respect and the specific conditions of the consent provided by identified individuals.

3.1.53 Proportional to the risks associated with, and the ethical sensitivity of the information, any sharing of data between research collaborators and research sites must be appropriate and secure.

3.1.54 When data is considered to be of historical, cultural and other long term value, researchers should seek consent for its perpetual retention, including re-use and sharing with others.

3.1.55 Where clinical research involves the use of materials of biological origin, records should be preserved for long enough to enable participants to be traced in the event that evidence emerges of late or long-term health-related effects.

3.1.56 In keeping with the design of the research and the consent obtained, data and biospecimens should be disposed of in a manner that is appropriate, safe and secure.

3.1.57 Researchers should assess and describe the risks to data security relating to storage, disclosure, sharing and disposal of digital data, and document the physical, network and system security controls that will be implemented to manage these risks.

3.1.58 Where data is sensitive and is to be stored online (even if only temporarily), researchers and reviewers must ensure that the service to be used is secure and has appropriate access controls.

3.1.59 Reviewers should recognise that expectations with regard to security and access should be proportional to the associated risks and ethical sensitivity of the research.

3.1.60 In the absence of justifiable ethical reasons (such as respect for cultural ownership or risks to the privacy of research participants) and to promote access to the benefits of research, researchers should collect and store data generated by research projects in such a way that they can be used in future research projects. Where a researcher believes there are valid reasons for not making data accessible, this must be justified.

**Banking and sharing of data**

While some data may be collected, aggregated and stored for a single purpose or activity, permission may sometimes be sought from participants to ‘bank’ their data for possible use in future research projects or to otherwise share it with other researchers.
To this end, data may be deposited in an open access repository or data warehouse, similar to an archive or library, and aggregated over time. Archived data can be made available for later analysis, unless access is constrained by restrictions imposed by the depositor/s.

The custodian of data may be the individual researcher or agency who collected the information, or an intermediary that manages data coming from a number of sources. In some cases, an independent custodian may be necessary to enable access by researchers or participants to the data while maintaining it in a coded form.

3.1.61 When data are being collected with the intention of sharing the data with other researchers (such as by adding them to an open access repository) or by adding them to a databank, researchers should clearly describe to reviewers how the collection of their research data will conform to the requirements for consent set out in paragraphs 2.2.14 to 2.2.18.

3.1.62 When collecting data with the intention of sharing the data with other researchers or for deposit in a databank, researchers should provide clear and comprehensive information to reviewers about:
(a) the form in which the data will be stored (identifiable, re-identifiable, non-identifiable);
(b) the purposes for which the data will be used and/or disclosed;
and whether they will seek:
(c) specific, extended or unspecified consent for future research (see paragraphs 2.2.14 to 2.2.16); or
(d) permission from a review body to waive the need for consent (see paragraphs 2.3.9 and 2.3.10).

3.1.63 The sharing of data with other researcher and the access to data from databanks must comply with conditions specified by the providers of the data; in particular, any conditions on the identifiability of the data (see 2.2.14 to 2.2.18).

3.1.64 Before publishing re-identifiable or non-identifiable data, or adding such data to a repository, researchers should consider the degree to which it may be possible for the data to become identifiable through efforts made by other researchers or third parties.

3.1.65 Shared or banked data that is stored in an identifiable form can sometimes be used in research that qualifies as negligible or low risk research; however, it cannot be used in research that is exempt from ethical review.

3.1.66 Researchers and custodians of the banked data should respect any confidentiality agreement with the participant and custodians should take every precaution to prevent the data becoming available for uses to which participants did not consent.
Element 5: Communication of research findings or results

Research across a range of fields and methodologies can generate findings or results of significance to participants and others. Some research (e.g. analysis of human biospecimens) can generate findings or results of significance to the health of the individual and, potentially, relatives and other family members.

The provision of research findings or results to participants can be a benefit, but it can also be a source of risk (e.g. psychological, social, legal). The approach taken to the communication findings and results must adhere to the ethical principles of justice, respect and beneficence discussed in Section 1 of this National Statement and consider the values and preferences of traditional custodians.

Communication of findings or results from research can be planned or anticipated. Communication of findings or results may be required or optional, appropriate or inappropriate depending on the nature of the research and other circumstances.

Communication of findings or results can also occur unintentionally (e.g. by third parties noticing the observations/recording of participants by a researcher).

Key questions include:
- Could the research generate findings or results of interest to participants?
- Could the findings or results be of significance to the welfare, wellbeing or future of participants or others?
- Are potential participants in the research forewarned of this possibility?
- Will the consent of participants be obtained to enable any planned or necessary disclosure of findings or results?
- Who will communicate the findings or results and how?
- Will the findings or results be disclosed to third parties?

3.1.67 Where information could be of significance to the health of participants, relatives or other family members, researchers should prepare and follow an ethically defensible plan to disclose or withhold findings or results of research (see Chapters 3.4 and 3.5 with respect to laboratory research involving human biospecimens and genomic research). Ethically defensible plans may also be relevant for other types of research.

3.1.68 An ethically defensible plan should:
(a) indicate whether the research will be likely to generate findings or results of significance to participants or others;
(b) clarify whether the researchers intend to disclose any findings or results to participants directly and which findings or results, if any, are returnable to participants or others (e.g. clinicians or relatives);
(c) confirm that participants will be advised in advance whether they will be offered the option to receive their findings or results;
(d) if applicable, enable participants to decide whether they wish to receive the findings or results and who else may be given the findings or results;
(e) in appropriate circumstances, set out a process for finding out whether family members wish to receive the information;
(f) outline how the findings or results will be provided in a manner that is appropriate and accessible;
(g) include the relevant expertise of the person who may be communicating the findings or results; and
(h) include measures to protect the level of privacy desired by participants.

Disclosure to third parties of findings or results

There can be situations where researchers have a legal, contractual or professional obligation to divulge findings or results to third parties. More ethically challenging are situations where researchers believe they have a moral obligation to disclose findings or results to third parties.

3.1.69 Where the potential disclosure of findings or results can be anticipated, researchers should identify:
(a) whether, to whom and under what circumstances the findings or results will be disclosed;
(b) whether potential participants will be forewarned that there may be such a disclosure;
(c) the risks associated with such a disclosure and how they will be managed; and
(d) the rationale for communicating and/or withholding the findings or results and the relative benefits and/or risks to participants of disclosure/non-disclosure.

3.1.70 Researchers should be aware of situations where a court, law enforcement agency or regulator may seek to compel the release of findings or results. In such circumstances, researchers should:
(a) have a strategy in place to address this possibility;
(b) advise participants of the potential for this to occur; and
(c) advise participants as to how the situation will be managed.

3.1.71 In circumstances where the potential for disclosing findings or results, or the imperative to do so, emerges after the research has commenced, researchers must promptly advise the reviewers and seek guidance from them.
Element 6: Dissemination of project outputs and outcomes

It is consistent with the ethical principles of respect, beneficence and justice to make the outputs or outcomes of research publicly available. Doing so is also a requirement of research integrity. The goal of dissemination of outputs/outcomes will be to make a positive contribution to knowledge or practice or to serve a public good. Common mechanisms for achieving this objective include publication in peer-reviewed journals or books, conference presentations, commissioned reviews for public bodies, or dissemination via other forms of media such as creative works and performances. The form of the disseminated outputs (e.g. a conference paper) will be shaped by the research field, the topic, the research design, researcher preference and experience. Publication of outcomes should not be withheld on the basis that they are negative or inconclusive. However, it is recognised that there may be justifiable reasons to delay or restrict the dissemination of the outputs or outcomes out of consideration for the privacy of the participants or other risk factors.

Key questions include:
- What is the plan for reporting, publication or other form of dissemination of the outputs/outcomes of the research?
- Will participants in the research be offered a timely and appropriate summary of the project outputs/outcomes?
- How will the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public?

3.1.72 Researchers should consider
(a) whether they intend to disseminate the outputs or outcomes widely in order to contribute to scientific, academic, professional or general knowledge or practice;
(b) whether there are any risk factors or commercial interests that might legitimately delay or restrict the dissemination the outputs or outcomes; and
(c) whether the risks of dissemination of the outputs or outcomes are justified by the benefits of dissemination (e.g. the public interest).

3.1.73 Researchers must ensure that reports of their research outputs or outcomes are accurate and complete and that they adhere to prevailing standards for ethical reporting, referencing and authorship.

3.1.74 Researchers should advise participants on the format and medium or media that will be used to disseminate outputs or outcomes of research to them and when such information about the outcomes will be made available to them.

3.1.75 Researchers should ensure that any outputs or outcomes disseminated to participants are provided in understandable language.
Element 7: After the project

Researchers continue to have ethical responsibilities after the project is completed. These responsibilities relate to disposal or retention of data and materials, potential secondary (later) use of the data and any necessary follow up or long term monitoring of research participants.

The *Australian Code for the Responsible Conduct of Research* establishes minimum retention periods for data and research materials. In accordance with this provision, institutions must establish guidelines with regard to the appropriate retention of data and materials for research conducted under the auspices of that institution. One of the important reasons for these requirements is to enable researchers to substantiate reported findings of research if they are challenged.

The design of a human research project must anticipate what will be done with the collected, generated or accessed data and research materials following completion of the research.

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<th>Key questions include:</th>
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<td>• Will the data or research materials only be retained for the minimum requisite period?</td>
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<td>• Do the data or research materials have cultural, historical or other significance that could warrant longer, or perpetual retention?</td>
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<tr>
<td>• Will the data or research materials be banked or added to a repository, such as an open access facility, for future use?</td>
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<tr>
<td>• Is there any necessary follow up or monitoring of research participants required and is this clear in the research plan and consent information?</td>
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3.1.76 The storage and subsequent disposal of the data and research materials must:

(a) maintain the confidentiality of individuals in accordance with any assurances made to them (e.g. during the consent process); and

(b) adhere to the ethical principle of respect for persons (e.g. with regard to culture and beliefs of the participants).

3.1.77 There may be sound ethical reasons supporting the banking of data for future use by either the original research team or for sharing the data with other researchers. Increasingly, researchers have been urged to make their data available through an open access arrangement. Any banking or sharing of data (e.g. via open access arrangements) must be anticipated in the research plan and in the processes and documentation used to obtain consent.

3.1.78 Data and research materials may be of cultural, historical or other significance such that they should be retained beyond the requisite period. Disposing of these data or materials without consideration of these factors would violate the ethical principle of respect. These matters should be appropriately addressed in the research plan and in consent processes and documentation.
Revised Chapter 3.5
CHAPTER 3.5: GENOMIC RESEARCH

Introduction

This chapter is about generating, gathering, collecting, conveying or using information that has hereditary implications in research involving participants and family members. It addresses the collection and use of biospecimens and/or genomic data for the purposes of this research.

Genomic research is characterised by the original intention of the investigation and the potential hereditary implications of the information that is generated by the investigations, irrespective of the source material. Genomic research is rapidly evolving and is not constrained by current methods or techniques for obtaining the information; however, a common element of genomic research is the sequencing of data or its use.

Genomic information can be predictive, unchanging, sensitive and familial. Genomic information has the unique character of being both specific to an individual and specific to relatives of that individual and, in some cases, of significance to human population groups such as groups that define themselves via their ancestral lineages.

Research results and information collected for genomic research may be significant for relatives of research participants. Relatives and other family members, such as partners and spouses, may have an interest in the participants’ genomic material, or in information the research generates, because testing that material or acquiring that information may create new options for life decisions, including those with the potential to improve their health or the health of their offspring. However, some family members may prefer not to be given such information, or even not to know of its existence.

Genomic research can reveal information about predispositions to disease. Although people with such a predisposition may not develop the disease, the information may have implications for their access to employment and education and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have similar implications for close relatives. In addition, genomic research can reveal information about previously unknown paternity or maternity or familial relationship.

This chapter is relevant to different types of genomic research (e.g. family studies, clinical research, population health research, health service research). Some research that falls within the broad description of genomic research does not involve information that is relevant to the future health of the individual participant and does not generate sensitivities for the individual, or his or her family or community. An example of this research is a population survey of preferences regarding disclosure of genomic information where survey results are non-identifiable.

Genomic research is considered to be high risk in ethics guidelines and practices related to research involving Indigenous peoples in Australia and internationally, thus requiring relevant on-going community consultation and active agreement on the part of communities and traditional owners.

As a general principle, research including genomics will require review by an HREC; however, if non-identifiable information is used and no linkage of data is planned, the research may be determined to carry low risk.

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3 E.g. (a) the germ line/germ cells (b) somatic cells or (c) a blend of germ line and somatic.
In genomic investigations, there may be a strong relationship between the research and clinical contexts such that there may be clinical implications of research results or findings. Where appropriate, researchers should also refer to clinical practice guidelines such as the NHMRC’s *Principles for the translation of ‘omics’– based tests from discovery to health care.*
Guidelines

Element 1: Research Scope, Aims, Themes, Questions and Methods

3.5.1 Genomic research that uses sequenced information should be designed with attention to what is necessary to achieve the aims of the research and to ensure that ethical issues that arise from activity outside the intended scope of the research are minimised by, for example, developing a list of genes that are excluded from analysis.

3.5.2 Genomic research should be designed to minimise the potential for misunderstanding and misuse of genomic information by those who may wish to use it for unrelated purposes.

3.5.3 Methods used in genomic research are not a static set, but are constantly evolving and, as they are developed and applied, may require ethical consideration on an ongoing basis. Therefore, the ethical principles and guidance in this chapter should be considered with reference to the new technologies as they are developed and applied.

Element 2: Recruitment

3.5.4 In addition to participants in genomic research identified as index cases (probands), relatives of these individuals who provide information or biospecimens for genomic research become participants in the research in their own right. Therefore, researchers should be aware of the possibility of de facto recruitment of relatives by virtue of association with a family member who has been recruited.

3.5.5 The recruitment process should avoid disclosure of information to a potential research participant as an inadvertent consequence of that process.

3.5.6 Where a potential research participant is not already known to the research team, it is ethically preferable for the index case (proband) to make the initial contact with a family member (rather than the researcher) for purposes of recruitment into research.

3.5.7 HRECs must consider the rationale for and review the information to be used in recruiting family members.

3.5.8 Researchers should respect differences between and within families regarding the willingness to communicate health information, the relative importance of privacy versus sharing of health information and other matters that may implicate cultural values (whether shared within the family or not).

3.5.9 Where researchers propose to generate or collect genomic information from individuals who are chosen because of their membership of a particular community, they should consult with appropriate community representatives.
Element 3: Consent

3.5.10 In considering the appropriate form and scope of consent and the most appropriate process for obtaining consent, researchers should consider:

(a) what information will be generated by the research;
(b) what may be discovered by the research;
(c) what will be deliberately excluded from the scope of the research;
(d) which, if any, of the findings of the research will be communicated to participants and, if so, how;
(e) what the health implications are of the information for participants and their relatives;
(f) whether there are any other implications for participants and their families of being given this information (e.g. insurance, employment, social stigma); and
(g) whether information generated by the research will be shared with other research groups.

3.5.11 Participants should be advised that information that they may be given about the likely impact of the genomic information may change over time as new knowledge/insight is gained.

3.5.12 Participants should be advised that publication or funding requirements may require submission of data to controlled access repositories that meet international security and safety standards for sharing with researchers globally.

3.5.13 Participants should be advised of the practical limitations associated with a decision to withdraw from genomic research after analysis of data has been conducted or biospecimens have been shared with other researchers as well as any other consequences that may follow from their withdrawal from the research.

3.5.14 Consent specific to the research may not be required:

(a) if the data or information to be collected/generated/accessed/used was previously collected and either aggregated or rendered non-identifiable;
(b) if prior consent was provided under the scope of a research program that encompasses the proposed research project; or
(c) if prior consent was provided in the clinical context for research that encompasses the proposed research project.

3.5.15 An opt-out approach (see 2.3.5) should not be used in genomic research.

3.5.16 Collection of family history may involve collection of data about other people who are not aware of the data collection; however, it is not practicable to obtain consent from all family members in a pedigree. Therefore, researchers should document who provided the family history and acknowledge that self-reported data about individuals and their families may not be accurate or complete.

3.5.17 Where participants or relatives have previously indicated that they prefer not to receive information, including information that is important for their health, the participant may contact the researcher if their preference changes.  

4 Note: This replaces the current requirement in NS 3.5.2(c).
Element 4: Data Collection and Management

This section covers the access to and collection, use, analysis, disclosure, storage, sharing and disposal of genomic data and information. The potential return of findings and results of genomic research is covered in 3.5.30-3.5.39, below.

3.5.18 Researchers should show regard for the potentially predictive and sensitive nature of genomic information.

3.5.19 Researchers should be sensitive to the contextual factors that determine the identifiability of genomic information, in particular the impact of the rarity of a genetic disorder or mutation on whether individuals or families could be identified.

3.5.20 For the purposes of a specific research project, information should be considered non-identifiable if there is no intention to link or match the information in such a way as to permit re-identification.

3.5.21 If inclusion of information in databases is a necessary component of the research or if information is to be shared for other research, efforts should be made to minimise the potential for re-identification.

3.5.22 Researchers should include in informational material comment on the potential for re-identifiability of the information generated by or used in the research.

3.5.23 Researchers receiving genomic information should not undertake nor permit attempts to re-identify the material or information or otherwise reduce the protection of the privacy of the participants.

3.5.24 Information generated or collected through genomic research should not be disclosed by researchers for uses unrelated to research; however, statutory or contractual duties may require participants to disclose the results of genetic tests or analysis to third parties (for example, insurance companies, employers, financial and educational institutions), particularly where results provide information about health prospects.  

3.5.25 Genomic information can sometimes be misused to stigmatise people or to discriminate against them unfairly. Researchers should therefore take special care to protect the privacy of participants.

3.5.26 Researchers should not share genomic information unless
(a) sharing data is consistent with the consent that has been obtained for the research project or for clinical purposes; or
(b) an HREC has judged that the conditions for waiver of the requirement for consent have been met (see NS 2.3.9-2.3.10); and
(c) the HREC has approved the transfer as set out in any transfer agreement that has been established for this purpose.

Researchers should note that Section 95AA of the Privacy Act 1988 (Cth) does not apply to genomic research.
3.5.27 Genomic data should be treated like other research data and retained for a period that permits the verification of the data and appropriate audit.

3.5.28 Genomic data should be stored in a file format that is appropriate to the character of the research.

3.5.29 Subject to the requirements of good research practice, genomic information and related biospecimens should be stored or disposed of in accordance with the project-specific consent provided or the governance policies of the relevant biobank.

Element 5: Communication of research findings or results

3.5.30 Return of findings and results relating to an individual participant depends on the contextual relevance of the findings; some genomic research findings must be returned, some findings may be returned and some findings should not be returned.

3.5.31 While participants have a strong interest in their own data, it is generally not expected that raw genomic data will be returned to participants.

3.5.32 Participants should be advised that research results or findings that may be returned will need to be validated according to applicable guidelines, e.g. at a NATA-accredited laboratory.

3.5.33 When designing the research project and in considering whether to return findings to participants, researchers should refer to the decision tree, below, for the principles/framework and then use the guidance below for developing an ethically defensible plan.

3.5.34 Any plan to return genomic research findings will benefit from a link with a clinical service and access to genetic counselling, specifying the expertise to which the project team might require access.

3.5.35 The person returning results or findings of significance for the health of the participant or relative should be the appropriate clinical service or, where such a service is not available, the participant’s clinician in consultation with the research team.

3.5.36 Where a result or finding may be of relevance to one or more relatives, it is the remit of the appropriate clinical service or the participant’s clinician to discuss with the participant the appropriateness of communicating these results or findings to relatives.

3.5.37 Over time there may be a substantive change in the understanding of the significance of the research results or findings. In such cases, researchers have a responsibility to provide the research cohort with the opportunity for each participant to re-consider their decision related to receiving results or findings during the period of the research project.

3.5.38 In all other cases, any obligation to return or further analyse or interpret genomic data related to participant information ceases at the end of the project.
Decision tree for the management of findings in genomic research and health care

**Note 1:** Clinicians who do not request an investigation or on whose behalf an investigation was not requested or who subsequently refer a patient to a different primary treating clinician do not have an obligation with respect to management of the findings of the investigation.

**Note 2:** The patient must be advised of the policy +. options addressing the return of findings including incidental findings.

**Note 3:** A "no" answer includes scenarios in which a non-validated test is performed in a NATA accredited lab or overseas equivalent AND in which a validated test is performed in a non-accredited lab. Situations in which this might occur include the development of diagnostic tests and research testing that has not been approved as part of a research project. In the first situation (test development), findings should not be returned. The second situation (unapproved testing) is contrary to ethical standards.

**Note 4:** The criteria and process must specify 1) that any findings must be verified by a NATA accredited lab; 2) which findings will be returned; 3) who will be consulted prior to the return of the findings; 4) to whom the findings will be returned.

**Note 5:** If the findings are not pertinent findings, then any return of findings will be based on the policy established by the research protocol and/or by international standards.

**Note 6:** Refer to guidance in this chapter regarding requirements related to consent for the return of findings from genomic research.

**Key Terms**

- **Pertinent findings:** Also known as primary findings, pertinent findings are those that were the primary objects of the investigation.

- **Secondary findings:** Findings that were not the primary target of the investigation, but were either specifically sought or are related to the primary target and anticipated as likely to arise.

- **Incidental findings:** Findings of potential clinical significance unexpectedly discovered during the investigation. NB: With respect to full spectrum discovery investigations and direct-to-consumer testing, one is explicitly searching for any and all findings and so no findings can be considered 'unexpected.'
Guidance for the Development and Evaluation of an Ethically Defensible Plan for the Potential Return of Findings and Individual Results from Genomic Research

General Requirements

3.5.39.1 Researchers must prepare and follow an ethically defensible plan to manage the disclosure or non-disclosure of genomic information of potential importance for the health of research participants or their relatives.

3.5.39.2 The ethically defensible plan must be approved by an HREC.

The Nature of Research Findings

3.5.39.3 Researchers should describe how potentially returnable findings may arise (where applicable). This description may include reference to the types of technologies that will be used to generate the findings.

3.5.39.4 As relevant, descriptions should include information on distinctions between
   (a) findings related to primary aims of the research (including individual test results); and
   (b) findings related to secondary aims of the research or findings that are unintended, unanticipated, inadvertent, incidental to or beyond the aims of the research.

3.5.39.5 Researchers should include information on the difference between clinical and research testing/findings and the need for further validation of any research findings and assessment of their clinical significance.

Step 1: Determination of Whether Findings Will Be Returned

Findings from genomic research fall into three categories:
   (a) findings that must be returned;
   (b) findings that may be returned;
   (c) findings that should not be returned.

The relevant factors to be considered to determine whether findings must, may or should not be returned include:
   (a) analytic (scientific) and clinical validity;
   (b) significance to the health of the participants/relatives;
   (c) clinical utility.

3.5.39.6 Researchers should recognise that, while standard practice for targeted genetic research is to return individual research results, standard practice for genomic research is to not return research findings to participants.

3.5.39.7 Where there will be any return of findings to participants, they should be advised as to which findings will be returned and which will not be returned, as follows:
(a) that researchers have an obligation to have a process in place for the return of findings that are of proven validity and of health significance to the participant or relative, subject to participant consent;
(b) that if researchers plan to return findings during the project that are of proven validity but are not of health significance to the participant or relative, they will need to justify this plan;
(c) that there is no obligation on researchers to look at or assess findings outside of the scope of the research; and
(d) that there is no ongoing responsibility on researchers to review findings of a research project after the project has been completed in order to discover or assess findings that may have become returnable due to later scientific advances.

3.5.39.8 Where unspecified collections by biobanks are involved, researchers should describe the role, if any, that any biobank involved in the collection, management or storage of any biospecimens used in genomic research will have in the return of findings. Researchers should note that there is no general expectation that there is a role for a biobank in the return of findings of genomic research.

3.5.39.9 Researchers must provide evidence of their awareness of any relevant institutional policies or procedures related to the return of findings to participants, including those of associated familial cancer centres or their equivalent.

3.5.39.10 Researchers should describe the resource requirements and infrastructure that are or will be put in place to support the process of return of findings, including resources that the research team, institution or external parties (e.g. clinicians and other experts) will need related to the provision of advice or counselling, the coordination of services and administrative matters.

**Step 2: Validation and Assessment of Findings**

This section applies to individual test results and any findings, whether primary, secondary or beyond the intended scope of the research.

3.5.39.11 Researchers should describe how any findings will be validated including reference to where the validation tests will ordinarily be conducted and any relevant distinctions between different types of validity.

3.5.39.12 Researchers should describe how the validated findings will be assessed for their potential health significance and clinical utility for the participant and/or relatives, including:
(a) who will be responsible for making these judgements, including any intention to refer participants to a clinician for this purpose;
(b) recommendations for finding the necessary expertise for making these judgements, if not within the expertise of the research team – a process that must
  (i) include the involvement of a clinical service with qualified genetics practitioners before and/or after the assessment; and
  (ii) be independent of the research team and any managing clinicians; and
(c) how the validated findings will be communicated to those whose expertise is required.
Step 3: Consent to Disclosure of Findings and Notification Requirements

3.5.39.13 Researchers should describe how consent for return of findings will be obtained and how it will enable participants’ decisions to receive or not to receive findings, including when, how, by whom the consent will be obtained and with recognition of:
   (a) the iterative character of consent (i.e. multiple time points) for return of this type of findings; and
   (b) the familial character of information and the consequent implications for relatives.

3.5.39.14 Researchers should describe the proposed communication process
   (a) with the participant;
   (b) with the appropriate clinical service or participant’s clinician (regarding the communication of the implications of the findings to the participant); and
   (c) with the authorised decision maker in the event of the death or incapacity of the participant.

3.5.39.15 The communication process should include:
   (a) who will be involved in communicating with the participant/clinician/authorised decision makers;
   (b) to whom the participant/clinician/authorised decision makers can address any follow up questions or concerns; and
   (c) what mechanisms and formats will be used to communicate information (including potential notification, disclosure and referral).

3.5.39.16 Researchers should provide participants with qualitative information regarding the likelihood that returnable findings will be discovered and whether an effective and beneficial (or harm reducing) intervention exists for the condition related to the findings.

3.5.39.17 If the participant has agreed to be notified of the existence of potentially relevant information and the option to receive this information, they should only be notified after the test validity and the potential utility of the information have been established.

3.5.39.18 Where feasible, researchers should indicate the timeframe for establishing the validity and potential utility of the relevant information.

3.5.39.19 A decision of the participant to not receive information on the research findings should be respected and confirmation of their preference not to receive information should not be routinely sought at a later point in time.

3.5.39.20 Researchers should be prepared to provide information to participants who, after indicating that they prefer not to receive information, including information that is important for their health, later change their preference and choose to receive the information.

3.5.39.21 Researchers should describe the access to genetic and clinical advice and counselling that will be provided, or clearly recommend to participants that they seek these services. Such advice and counselling should be provided by professionals with appropriate training, qualifications and experience.
3.5.39.22 Researchers should specify where these resources are located and confirm that sufficient resources are available.

**Privacy Issues Specific to Genetic Information**

3.5.39.23 Researchers should consider the identifiability of information and data linkage issues in the context of return of genomic research findings, with specific attention to the impact of the design and implementation of the research and other current or projected activities that may require the use of the information/findings that are potentially returnable.

3.5.39.24 Researchers should advise participants of the potentially identifiable status of genetic information.

3.5.39.25 Researchers should describe the process for protection of privacy in accordance with participant preferences, how differences in the preferences of participants will be accommodated and how any conflicts (e.g. between family members) will be managed.

3.5.39.26 Researchers should consider how research data will be stored in the event of the need for future analysis/testing and disclosure to participants.
Glossary

New terms added
Glossary – New Terms

Co-researcher
One or more participants (or a particular sub-group of participants) who make/s a significant contribution to the planning, design, implementation or outputs of a research project, including the collection, analysis or interpretation of data. Examples of co-researcher contributions include where participants contribute expertise, such as their cultural knowledge of mores and local practices, or their personal insights into local conditions, special interests (e.g., gaming), or social identities or contexts (e.g. young people living in out-of-home care, community activists or people who identify as LGBTIQ).

Genomic data
Raw data, processed data or information that has been subject to a process of critical analysis and/or interpretation to assign meaning in the context of genomic research.

Genomic research
Research with the potential for hereditary implications which may range from single gene genetic research to whole genome sequencing and any other ‘omic’ research (e.g. exomic, proteomic, etc) with potential hereditary implications. Genomic research includes the full scope of ‘genetic’ research.

Index case
The original patient or research participant that stimulates investigation of other members of the family. This person is also referred to as the ‘proband’.

Innovation
In the research context, the introduction of one or more novel elements of an intervention that represent/s a substantive departure from the spectrum of standard care or service delivery. An innovation may apply modalities or strategies used and tested in one domain to a novel application. An innovation may or may not be therapeutic in intent or effect and may or may not be considered to be experimental; however, a condition of research involving an innovation is that the safety, efficacy, or effectiveness of the innovation in the context in which it is used is not known at the onset of the research.

Intervention
Where researchers intentionally expose participants to a change in their circumstances with the further intention to evaluate the impact of that change in one or more outcome measures. The intervention can be a medical or health procedure, a service intervention, an educational or social policy, a therapeutic strategy, or an approach to provision of information that is introduced and manipulated, controlled or directed by the researcher.

Mutations
Genetic changes that can be investigated or discovered in the form of

- **Germ line mutations**, which involve inherited or *de novo* variations or mutations that occur in germ cells implicating one or more genes known to cause or predispose a person to disease (e.g. BRCA1)
- **Somatic mutations**, which involve acquired variations or mutations in one or more genes within tissues (e.g. tumours with BRAFV600E)
Relatives
Persons related by blood to the index case, as distinguished from family members who are persons who may or may not be related by blood, but who may be affected by information with hereditary implications.

Research findings
Information that becomes known as a result of the research. Research findings may take the form of
- Findings related to primary aims of the research (including individual test results)
- Findings related to secondary aims of the research or that are unintended, unanticipated, inadvertent or incidental to the aims of the research.

Validity
In the context of genomic research findings or individual test results, a judgement about the likely accuracy of the findings or results, as measured by National Association of Testing Authorities (NATA) accredited testing or its equivalent. Validity may refer to the pathology processes establishing the analytic validity and clinical validity of a testing method and/or the use of an accredited test to confirm the presence of a variant found in the research.
Consequential changes to Section 5

Please note that only the text in red has been added, deleted or modified and that only this text is the subject of public consultation.
SECTION 5: PROCESSES OF RESEARCH GOVERNANCE AND ETHICAL REVIEW

Human research encompasses a wide range of activities with an equally wide range of risks and potential benefits. The National Statement allows for different levels of ethical review of research, reflecting the difference in degree of risk involved (see Chapter 2.1: Risk and benefit).

This Section sets out the processes by which institutions establish, conduct and oversee those different levels of ethical review, and includes the operations of Human Research Ethics Committees (HRECs). The section also describes other processes of research governance that must be in place if the ethical review of research is to be undertaken well. These are considered only briefly, as they are more fully set out in the Australian code for the responsible conduct of research.

CHAPTER 5.1: INSTITUTIONAL RESPONSIBILITIES

Guidelines

Research governance

5.1.1 Institutions must see that any human research they conduct or for which they are responsible is:
(a) designed and conducted in accordance with the Australian code for the responsible conduct of research; and
(b) ethically reviewed and monitored in accordance with this National Statement.

5.1.2 Each institution needs to be satisfied that:
(a) its human research meets relevant scholarly or scientific standards;
(b) those conducting its human research:
   (i) are either adequately experienced and qualified, or supervised;
   (ii) understand the need to assess risks to their own safety and that of participants; and
   (iii) are free to withdraw from research on conscientious grounds.

5.1.3 Institutions may establish their own processes for ethical review of research, or use those of another institution.

5.1.4 Whichever option under 5.1.3 is adopted, institutions need to be satisfied that processes are in place for:
(a) managing conflicts of interest (Chapter 5.4);
(b) monitoring research (Chapter 5.5);
(c) handling complaints (Chapter 5.6); and
(d) ensuring accountability (Chapter 5.7).

5.1.5 Institutions should use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.
Processes for ethical review

5.1.6 The following types of research require review by a Human Research Ethics Committee (HREC):
(a) all research that involves more than low risk;
(b) research falling under the following chapters (except where research on collections of non-identifiable data under these chapters satisfies the conditions for exemption from review – see paragraphs 5.1.22 and 5.1.23):
- Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials, and innovations
- Chapter 3.5: Human genetics
- Chapter 4.1: Women who are pregnant and the human fetus
- Chapter 4.4: People highly dependent on medical care who may be unable to give consent
- Chapter 4.5: People with a cognitive impairment, an intellectual disability, or a mental illness
- Chapter 4.7: Aboriginal and Torres Strait Islander Peoples and some categories of research falling under
- Chapter 4.6: People who may be involved in illegal activities (see first bolded paragraph for details).

5.1.7 For research that carries only low risk (see paragraph 2.1.6) and does not fall under any of the chapters listed in paragraph 5.1.6, institutions may choose to establish other levels of ethical review. These levels are described in paragraphs 5.1.18 to 5.1.21.

5.1.8 Research that carries only negligible risk (see paragraph 2.1.7) and meets the requirements of paragraphs 5.1.22 and 5.1.23 may be exempted from ethical review.

Legal protection for those involved in ethical review of research

5.1.9 Institutions should provide an assurance of legal protection to all those involved in ethical review of research, for liabilities that may arise in the course of bona fide conduct of their duties in this capacity.

Oversight and review of ethical review procedures

5.1.10 Institutions that set up levels of ethical review other than HREC, as described in paragraphs 5.1.18 to 5.1.23, must establish criteria for allocating research to these different levels of review (including exemption from review), taking into account Chapter 2.1: Risk and benefit. These criteria must be readily accessible to all those involved in the conduct and review of research.

5.1.11 The ethical values and principles in this National Statement should be the basis on which institutions establish different levels of ethical review, allocate different kinds of research to them, and review those allocations.

5.1.12 Institutions must monitor any processes of ethical review of low risk research to ensure those processes continue to provide sufficient protection for participants.
5.1.13 Institutions should regularly assess all their ethical review processes, including the criteria for allocating research to different levels of review, to ensure that those processes continue to enable the institution to meet its responsibilities under this National Statement.

5.1.14 Where possible this assessment should be informed by the documented experience of research participants and/or by involving participants or the wider community in the assessment.

5.1.15 Institutions should also remain alert to emerging ethical issues in any area of human research that may warrant changing the level of ethical review required.

5.1.16 To enable assessment of their ethical review processes, institutions should prepare and make readily accessible regular reports on all of those processes.

5.1.17 Institutions should have in place an auditing process to confirm that:
   (a) research in their institution is being reviewed at the levels of review their criteria require;
   (b) research is being exempted from review only in accordance with the criteria set out in paragraphs 5.1.22 and 5.1.23.

Research involving no more than low risk

5.1.18 Institutions that establish any non-HREC levels of ethical review for low risk research must have the resources and capacity to carry out such review competently and professionally.

5.1.19 Where institutions establish such non-HREC levels of ethical review for low risk research, that review must:
   (a) be carried out by people who are familiar with this National Statement and have an understanding of the ethical issues that can arise in the research under review;
   (b) be informed by Section 1: Values and Principles of Ethical Conduct, Section 3: Ethical Considerations in the Design, Development, Review and Conduct of Research and Section 4: Ethical Considerations Specific to Participants;
   (c) take account of researchers’ judgements as to whether their research is suitable for review by a non-HREC process;
   (d) have due regard to relevant privacy regulation.

5.1.20 The levels of ethical review referred to in paragraph 5.1.18 may include, but need not be limited to:
   (a) review or assessment at departmental level by the head of department;
   (b) review or assessment by a departmental committee of peers (with or without external or independent members);
   (c) delegated review with reporting to an HREC; or
   (d) review by a subcommittee of an HREC.

5.1.21 Those reviewing research at a non-HREC level must refer to an HREC any research they identify as involving more than low risk.
Research that can be exempted from review

5.1.22 Institutions may choose to exempt from ethical review research that:
(a) is negligible risk research (as defined in paragraph 2.1.7); and
(b) involves the use of existing collections of data or records that contain only non-identifiable data about human beings.

5.1.23 Institutions must recognise that in deciding to exempt research from ethical review, they are determining that the research meets the requirements of this National Statement and is ethically acceptable.

HRECs: research involving more than low risk

5.1.24 Each institution that conducts human research involving more than low risk must ensure that this research is reviewed and approved by an HREC that is constituted and functioning in accordance with this National Statement, whether or not that HREC is established by the institution.

5.1.25 Institutions that establish HRECs are responsible for ensuring that those HRECs are established and continue to operate in accordance with this National Statement.

5.1.26 Health care and medical institutions should establish standards to determine when an innovative intervention requires systematic investigation to determine its safety and efficacy. When such systematic investigation is required, it should be treated as clinical research needing formal consideration by an HREC.

Establishment of HRECs

5.1.27 Institutions that individually or jointly establish HRECs should adequately resource and maintain them. Resourcing should be sufficient to enable HRECs:
(a) to satisfy the requirements for sound ethical review (see paragraph 5.1.38);
(b) to communicate well with researchers (see paragraphs 5.2.14 to 5.2.16);
(c) not to charge fees where doing so would discourage research the institution has an obligation to support.

5.1.28 When establishing an HREC, an institution should set out and publicise its terms of reference, including:
(a) the scope of its responsibilities for ethical review;
(b) its relationship to other processes of research review;
(c) its relationship to non-affiliated researchers;
(d) its institutional accountability;
(e) its mechanisms of reporting;
(f) categories of minimum membership; and
(g) remuneration, if any, for members.

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6 Where the context is the establishment and maintenance of an HREC, ‘institutions’ also includes any body or agency that establishes an HREC but does not conduct human research.
5.1.29 Where an institution has established an HREC, the institution is responsible for ensuring that:

(a) members have relevant experience and/or expertise;
(b) members undertake:
   (i) appropriate induction, which could include mentoring by a current HREC member, and
   (ii) continuing education;
(c) review of research proposals is thorough;
(d) review processes and procedures are expeditious;
(e) decisions are transparent, consistent, and promptly communicated;
(f) actual and potential conflicts of interest that may affect research and its review are identified and managed (see Chapter 5.4: Conflicts of interest);
(g) membership of the HREC is made public in annual reports or by other routine processes, and is available to researchers submitting research proposals to that HREC;
(h) good communication between the institution/s, the HREC and researchers is promoted;
(i) the workload of the HREC does not compromise the quality and timeliness of ethical review; and
(j) any institution using the HREC can be assured the HREC is operating in accordance with this National Statement.

Composition of HRECs

5.1.30 The minimum membership of an HREC is eight. As far as possible:

(a) there should be equal numbers of men and women; and
(b) at least one third of the members should be from outside the institution for which the HREC is reviewing research.

5.1.31 This minimum membership is:

(a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under this National Statement;
(b) at least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;
(c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;
(d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion;
(e) at least one lawyer, where possible one who is not engaged to advise the institution; and
(f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

5.1.32 No member may be appointed in more than one of the categories listed in paragraph 5.1.31, but institutions are encouraged to establish a pool of inducted members in each category. These members may attend meetings as needed to meet minimum HREC requirements, and may also be available to provide expertise for the research under review.

5.1.33 Wherever possible one or more of the members listed in 5.1.31 should be experienced in reflecting on and analysing ethical decision-making.
5.1.34 The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.

**Appointment of HREC members**

5.1.35 Members should be appointed to an HREC using open and transparent processes. Institutions should consider reviewing appointments to the HREC at least every three years.

5.1.36 Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion.

5.1.37 Members should be provided with a formal notice of appointment.

**HREC procedures**

5.1.38 An institution that establishes an HREC should ensure that the HREC establishes, implements and documents working procedures to promote good ethical review, including procedures for:

- (a) frequency of meetings;
- (b) attendance at meetings;
- (c) conduct and structure of meetings and deliberations;
- (d) preparation of agendas and minutes;
- (e) timely distribution of papers before meetings;
- (f) presentation of applications for ethical review;
- (g) timely consideration and review of applications;
- (h) managing conflicts of interest (see paragraphs 5.4.1 to 5.4.6);
- (i) communicating with researchers, including face to face, by telephone and in writing (including email) (see paragraphs 5.2.14 to 5.2.16);
- (j) reporting on its activities to the institution;
- (k) methods of decision making;
- (l) prompt notification of decisions;
- (m) record keeping (see paragraphs 5.2.25 to 5.2.29);
- (n) monitoring of approved research (see paragraphs 5.5.1 to 5.5.5);
- (o) reporting and handling of adverse events;
- (p) receiving and handling of complaints (see paragraphs 5.6.1 to 5.6.7);
- (q) advising the institution/s of decisions to withdraw ethical approval of a research project (see paragraphs 5.5.7 to 5.5.9);
- (r) attendance, as observers, of people other than members or researchers (see paragraph 5.2.20) at meetings;
- (s) fees, if any, to be charged; and
- (t) appropriate confidentiality of the content of applications and the deliberations of review bodies.
Insurance

5.1.39 Institutions must be satisfied that sponsors of trials have made the indemnity or insurance and compensation arrangements required by CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices and the TGA, as appropriate.

5.1.40 In addition to the requirements in paragraph 5.1.39, institutions must also have arrangements to compensate participants for harm resulting from negligence in research to which the documents listed in 5.1.39 apply.
CHAPTER 5.2: RESPONSIBILITIES OF HRECS, OTHER ETHICAL REVIEW BODIES, AND RESEARCHERS

Guidelines

Review body procedures

5.2.1 Institutions that set up non-HREC levels of ethical review should ensure that they have good working procedures for those levels. These should include the procedures from paragraph 5.1.38 and paragraphs 5.2.26 to 5.2.29 that are necessary for sound review at each of those levels.

Review body member responsibilities

5.2.2 Each member of an ethical review body is responsible for deciding whether, in his or her judgement, a proposal submitted to the review body meets the requirements of this National Statement and is ethically acceptable.

5.2.3 To fulfil that responsibility, each member of a review body should:
   (a) become familiar with this National Statement, and consult other guidelines relevant to the review of specific research proposals;
   (b) prepare for and attend scheduled meetings of the review body or, if unavailable, provide opinions on the ethical acceptability of research proposals before meetings, subject to institutional policies on absences; and
   (c) attend continuing education or training programs in research ethics at least every three years.

5.2.4 Members of a review body should disclose to it any actual or potential conflict of interest, including any financial or other interest or affiliation, that bears on any research coming before the review body (see paragraph 5.4.5).

Researcher responsibilities

5.2.5 In each research proposal, the researcher/s should demonstrate that the research has merit and reflects the ethical values of justice, beneficence and respect for humans (see paragraph 1.1).

5.2.6 For relevant research, researchers should show that the research meets the relevant requirements of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices, and the TGA.

5.2.7 Research proposals should be clear and comprehensive, and written in lay language.

5.2.8 A researcher should disclose to the review body the amount and sources or potential sources of funding for the research.

5.2.9 A researcher developing or designing a research proposal involving two or more institutions should inform them all at an early stage in this process.
5.2.10 A researcher should keep an auditable record of any research he or she is undertaking that is exempted from ethical review in accordance with paragraphs 5.1.22 and 5.1.23.

5.2.11 A researcher should disclose to the review body any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on the research (see Chapter 5.4: Conflicts of interest). For relevant research, this disclosure should specify:
   (a) any business, financial or other similar association between a researcher and the supplier of a drug or surgical or other device to be used in the research; and
   (b) any restrictions on publication of research findings.

5.2.12 When reporting the research, a researcher should again disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, that bears on the research.

5.2.13 For researcher responsibilities in relation to monitoring, see Chapter 5.5: Monitoring approved research.

Good communication between review bodies and researchers

5.2.14 Good ethical review requires open communication between review bodies and researchers, and a shared commitment to the review process. The process should not be adversarial. Institutions should encourage this shared commitment by promoting:
   (a) awareness of this National Statement among researchers; and
   (b) ready accessibility of review bodies and their staff to researchers.

5.2.15 Misunderstandings can often arise when only written communication is used. From the outset review bodies should encourage informal communication with researchers, and should consider face-to-face meetings to resolve issues about research proposals that have not been resolved by written or telephone communication.

5.2.16 Open communication of these kinds has implications for the resourcing of review bodies (see paragraphs 5.1.18, and 5.1.27).

Participants’ interests

5.2.17 Information about research should be presented to participants in ways that help them to make good choices about their participation, and support them in that participation. These ways must take into account:
   (a) whether the information is best communicated through speech, writing, some other way, or a combination of these;
   (b) the need for accurate and reliable translation (written and/or oral) into a participant’s first language or dialect;
   (c) culture and its effects on how language (English or other) is understood;
   (d) educational background and level;
   (e) age;
   (f) visual, hearing or communication impairment.
5.2.18 In any clinical research, especially clinical trials, a review body should be satisfied that research participants are adequately informed of the funding arrangements of the research and given the option of knowing the details of any capitation payments to researchers or clinicians.

5.2.19 A review body should consider consulting a participant advocate to help it assess whether a proposal under consideration adequately provides for participants’ decision making and understanding. Researchers or experts at review body meetings.

5.2.20 A review body (HREC or other) may invite researcher/s, and researchers may request, to be present for discussion of their proposed research.

5.2.21 A review body may seek advice from experts to help in considering a research proposal (e.g. as in paragraph 5.1.33). Such experts should be bound by the same confidentiality requirements as the review body members. Any conflicts of interest they may have should be disclosed and managed (see paragraphs 5.4.1 to 5.4.6).

5.2.22 Communication between a research sponsor and a review body should be avoided where it may, or may be perceived to, influence the ethical review and approval of the project.

Making and communicating decisions

5.2.23 A review body may approve, request amendment of, or reject a research proposal on ethical grounds.

5.2.24 The review body must clearly communicate its decision to the researcher/s:
   (a) Where a proposal is approved, communication must be in writing (which may include email) and should include an explicit statement that the proposal meets the requirements of this National Statement.
   (b) Where amendments are requested, communication may be written or, where appropriate, informal (see paragraph 5.2.15). Reasons should be given for the requested amendments.
   (c) Where a proposal is rejected, communication of the rejection must be in writing (which may include email) and should include reasons linked to this National Statement.

Documents and records

5.2.25 All documents and other material used in recruiting potential research participants, including advertisements, letters of invitation, information sheets and consent forms, should be approved by the review body.

5.2.26 A review body should maintain a record of all research proposals received and reviewed, including at least the:
   (a) name/s of the institution/s to which the research approval is provided;
   (b) project identification number/s;
   (c) name/s of principal researcher/s;
   (d) title of the project;
   (e) correspondence between the review body and the researcher about the review;
(f) acceptance or rejection of any changes to the proposal;
(g) proposed date of completion of the proposal;
(h) formal advice of final ethical approval or non-approval, with date;
(i) terms and conditions, if any, of approval of any proposal;
(j) duration of the approval;
(k) name of any other review body whose opinion was considered;
(l) mechanisms to be used to monitor the conduct of the research; and
(m) relevance, if any, of the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.

5.2.27 In addition, a review body should retain on file a copy of each research proposal and application for ethical approval, including any information sheets, consent forms or relevant correspondence, in the form in which they were approved.

5.2.28 A review body should record decisions about approval, amendment or rejection of proposals in written or electronic form, with reasons for those decisions, linking those reasons to this National Statement.

5.2.29 Where more than one review body has reviewed a research proposal, each such review body should record, as far as possible (see paragraph 5.3.3):
(a) details of other review body/ies involved;
(b) the decision/s of each other review body; and
(c) details of any amendments required by each other review body.

HREC meetings

5.2.30 As far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend (see paragraphs 5.1.29 to 5.1.32). Meeting papers should be provided enough in advance to enable members to be fully informed.

5.2.31 Decisions by an HREC about whether a research proposal meets the requirements of this National Statement must be informed by an exchange of opinions from each of those who constitute the minimum membership (see paragraph 5.1.30). This exchange should, ideally, take place at a meeting with all those members present.

5.2.32 Where there is less than full attendance of the minimum membership at a meeting, the Chairperson should be satisfied, before a decision is reached, that the views of those absent who belong to the minimum membership have been received and considered.

5.2.33 An HREC should endeavour to reach decisions by general agreement. This need not involve unanimity.
CHAPTER 5.5: MONITORING APPROVED RESEARCH

Introduction

Monitoring of research here refers to the process of verifying that the conduct of research conforms to the approved proposal. Responsibility for ensuring that research is reliably monitored lies with the institution under which the research is conducted.

Mechanisms for monitoring can include:

(a) reports from researchers;
(b) reports from independent agencies (such as a data and safety monitoring board);
(c) review of adverse event reports;
(d) random inspections of research sites, data, or consent documentation; and
(e) interviews with research participants or other forms of feedback from them.

Guidelines

Monitoring approved research

5.5.1 Each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored.

5.5.2 The frequency and type of monitoring should reflect the degree of risk to research participants and monitoring arrangements should be commensurate with the risk, size and complexity of the research.

5.5.3 For each clinical trial, institutions and review bodies should ensure that there are appropriate mechanisms for reporting and reviewing serious adverse events, serious adverse drug reactions (ADRs), serious unexpected suspected adverse reactions (SUSARs), and/or serious adverse device events relevant to the scope of their monitoring responsibility.

5.5.4 For each clinical trial of sufficient size and complexity, review bodies should seek information on the use of a Data and Safety Monitoring Board (DSMB) and ensure that there is a mechanism for informing the review body of any relevant emerging data from the DSMB.

5.5.5 For clinical trials other than those in 5.5.4, there should be (an) identified person/s or committee with suitable expertise to assist and advise the institution and/or review body in carrying out their safety monitoring responsibilities.

5.5.6 Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report, as appropriate, relevant events or outcomes promptly to the relevant institution/s and/or ethical review body/ies, and take prompt steps to deal with any unexpected risks.

5.5.7 Researchers are responsible for notifying the review body that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.
5.5.8 At regular periods – reflecting the degree of risk, and at least annually and at the completion of the project – researchers should provide reports to the relevant review body/ies and institution/s, including information on:

(a) progress to date, or outcome in the case of completed research;
(b) maintenance and security of records;
(c) compliance with the approved proposal; and
(d) compliance with any conditions of approval.

5.5.9 The granting and continuation of ethical approval of clinical trial research must be on the condition that the researchers:

(a) conduct the trial in compliance with the approved protocol;
(b) provide reports of the progress of the trial and any safety reports as indicated in this chapter and in accordance with the manner and form specified by the review body;
(c) submit for approval any amendments to the protocol, including but not limited to amendments that:
   (i) are proposed or undertaken in order to eliminate immediate risks to participants;
   (ii) may increase the risks to participants; or
   (iii) significantly affect the conduct of the trial;
(d) inform the review body as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the trial or may indicate the need for amendments to the trial protocol;
(e) for trials with implantable medical devices, confirm the existence of, or establish, a system for:
   (i) tracking the participant, with consent, for the lifetime of the device; and
   (ii) reporting any device incidents to the TGA.

Discontinuation or suspension or cessation of research

5.5.10 Researchers should inform the relevant institution/s, the review body/ies that approved the research and, wherever possible, the research participants, if the research project is to be discontinued before the expected date of completion, and why. For research at more than one site, or research where there has been multiple ethical review, it must be clearly established, before the research begins, how this information will be communicated.

5.5.11 Where a review body finds reason to believe that continuance of a research project will compromise participants’ welfare, it should immediately seek to establish whether ethical approval for the project should be withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.

5.5.12 It may be unethical for a researcher to continue a trial if:

(a) there are or have been substantial deviations from the trial protocol;
(b) side-effects of unexpected type, severity, or frequency are encountered; or
(c) as the trial progresses, one of several treatments or procedures being compared appears to be so much better or worse than the other/s that the continuation of the trial would disadvantage some of the participants. The clearer it becomes that one treatment is
substantially better or worse than the others, the stronger the need to consider discontinuing the trial.

5.5.13 Where ethical approval for a research project is withdrawn:

(a) the researcher, the institution/s and, where possible, the participants should be informed of the withdrawal;
(b) the institution must see that the researcher promptly suspends the research and makes arrangements to meet the needs of participants; and
(c) the research may not be resumed unless either
   (i) the researcher subsequently establishes that continuance will not compromise participants’ welfare; or
   (ii) the research is modified to provide sufficient protection for participants, the modification is ethically reviewed, and the modified research is approved.

5.5.14 If an institution or review body considers that urgent suspension of research is necessary before the process described in paragraphs 5.5.7 and 5.5.8 is undertaken, the instruction to stop should come via the management of the institution.

5.5.15 In the light of reports received under paragraph 5.5.3 and paragraph 5.5.5, review bodies may require researchers to amend research procedures to protect participants. If such amendments cannot achieve that end, a review body may rely on the provisions of paragraphs 5.5.6 to 5.5.9.