

SECTION 5: RESEARCH GOVERNANCE AND ETHICS REVIEW

INTRODUCTION

[revised introduction] The conduct of ethical research requires a comprehensive, well-designed and fully implemented framework for governance of research in the institutions¹ under whose auspices the research is conducted. This framework should encompass research culture, planning and support for research, and processes for the review, authorisation, conduct and monitoring of research. It should be grounded in accepted principles of research integrity.

Requirements and guidance for the integrity and the responsible conduct of research are more fully addressed in the [Australian code for the responsible conduct of research](#) and supporting guidance.

This Section describes the core responsibilities of research governance and sets out the processes by which institutions establish, conduct and oversee different levels of ethics review. The Section also covers the operations of Human Research Ethics Committees (HRECs), monitoring responsibilities, conflicts of interest, complaints management and accountability.

Chapter 5.1: Governance responsibilities of institutions

INTRODUCTION

[new introduction] All research should be developed, reviewed, authorised, conducted and monitored in accordance with a research governance framework. In most cases, this framework will be developed and implemented in one or more institutions with responsibility for the research.

A key component of a research governance framework is the requirement that research must undergo ethics review. The National Statement supports the principle of proportionate review and enables a variety of review processes that reflect the level of risk that is associated with a specific research project (see Chapter 2.1).

Research ethics committees are a core feature of research governance around the world. Consistent with international models, Australian HRECs have broad membership and a defined set of roles to play in the oversight of research. HRECs also have functions that are imposed by privacy legislation and by regulatory agencies such as the Therapeutic Goods Administration (TGA). While these roles are often conferred on an HREC by an institution that has established it, some functions of an HREC are conferred directly by legislation or regulation and can be exercised independent of a host institution.

As a consequence of the type of research that an HREC reviews, as well as the nature or structure of the institution to which an HREC is accountable, there can be significant differences in the scope of its responsibilities and the processes that an HREC employs to carry out its functions. An example of this can be seen in the differences between HRECs operating in the publicly funded health sector (e.g. public hospitals), those operating in the private health sector and those operating in universities.

¹ In this document, the term 'institution' is used to include both traditional healthcare and educational institutions, such as hospitals and universities, and any organisation, government agency or other entity that has responsibility for oversight of the conduct and/or the review of research. However, it is recognised that not all institutions will have the infrastructure or resources necessary to perform all of the functions that are attributed to institutions in Section 5.

Similarly, the scope of HREC review may differ: some HRECs conduct ethics review exclusively, while others include technical or scientific review within their remit. Institutions with HRECs of the first type often delegate technical or scientific review to sub-committees that report to the HREC.

Finally, there are a variety of models used by institutions for the review of research that does not require review by an HREC. These are discussed in Chapter 5.1 at 5.1.X–5.1.X.

GUIDELINES

Research governance

1. *[revised 5.1.1]* Institutions must develop and adhere to a research governance framework grounded in accepted ethical principles and principles of research integrity as set out in the National Statement and the [*Australian code for the responsible conduct of research*](#).
2. *[new]* Institutions must ensure that any human research they conduct, or for which they are responsible, is designed, reviewed, approved, authorised, conducted and monitored in accordance with their research governance framework.
3. *[revised 5.1.2]* Each institution should be satisfied that the human research for which it is responsible meets relevant ethical and scholarly or scientific standards.
4. *[new]* Each institution should be satisfied that the human research for which it is responsible adequately takes account of consumer and community perspectives, with reference, where relevant, to NHMRC's *Statement on Consumer and Community Participation in Health and Medical Research*.
5. *[revised 5.1.5]* Institutions should adopt and publish clearly formulated, policies and procedures for ethics review and approval and institutional authorisation of research.
6. *[new]* Institutions should clarify their policy and procedures for the review, approval and authorisation of non-research activity, including the processes used to determine whether a project is considered research or non-research activity, such as evaluation, training, quality assurance or audit.

Ethics review policy and process

7. *[revised 5.1.3]* Institutions may establish their own processes for ethics review of research, or accept the review of an external ethics review body.
8. *[new]* When accepting the review of an external ethics review body, institutions should ensure that the review process is consistent with the requirements of the National Statement (or, if a review from another country, an equivalent international standard).
9. *[new]* When considering accepting the review of another institution's ethics review process, including the review of an external review body, institutions should follow the guidelines in Chapter 5.5.

Risk levels and corresponding review pathways

10. *[new]* All research should be assessed for level of risk, in accordance with the guidance provided in Chapter 2.1.

11. *[new]* If a research project is considered to carry moderate to high risk, it should be reviewed by an HREC, regardless of any proposed approaches to minimising or mitigating any risks associated with the research.
12. *[new]* For research that carries only minimal risk (see 2.1.6), institutions may choose to establish other processes for review. These processes may include:
 - a. review by a subcommittee or the Chair of an HREC;
 - b. delegated review by a committee or person(s) within an institution;
 - c. in a university setting, review or assessment at departmental level by the head of department;
 - d. in a university setting, review or assessment by a departmental committee of peers (with or without external or independent members); and
 - e. acceptance of a review process external to the institution (see Chapter 5.5).
13. *[revised 5.1.18]* Institutions that establish non-HREC pathways for ethics review must have the resources and capacity to carry out such review competently and professionally.
14. *[revised 5.1.19]* Where institutions establish non-HREC pathways for ethics review, 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 Related to Potentially Vulnerable Participants in Research;
 - 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 and other legal standards; and
 - e. include clear criteria for referring review to an HREC where greater than minimal risk is identified during non-HREC review.

Research that can be exempted from review

15. *[new]* Some research may be eligible for exemption from review. Where appropriate, exemption is granted, or not, by the institution responsible for the research after consideration of the guidance provided in Chapter 2.1 and Chapter 3.1, Element 4.
16. *[revised 5.1.22–5.1.23]* Research that may be eligible for exemption includes research that:
 - a. carries minimal or no risk to participants, researchers or the community and satisfies one or more of the conditions in (b) – (e), below;
 - b. involves the use of collections of biospecimens, information or data
 - i. from which personal identifiers have been removed prior to use by the researchers and where there is no plan to re-identify those with whom the information is associated; or
 - ii. involves the use of biospecimens, information or data originally obtained for non-research purposes or for research other than the current research proposal where unspecified ('broad') consent (see 2.2.14(c)) from the participants for the storage, maintenance and research use of their biospecimens, information or data has been documented;

- c. is restricted to surveys, interviews, and observation of public behaviour using information that was or will be collected and recorded without personal identifiers and does not involve sensitive content or contexts;
- d. is conducted in established or commonly accepted educational or training settings and that involves normal educational or training practices, such as research on instructional techniques already in use or classroom management; and/or
- e. is conducted by or on behalf of a government department or agency, using data collected or generated by the government for non-research purposes, and the use of the information adheres to relevant privacy standards. This may include research that is designed to observe, analyse, evaluate or improve public service or public benefit programs.

17. *[new]* Any research that is exempted from review must be listed on a publicly accessible website by the entity conducting or sponsoring the research before the research commences.

18. *[new]* An investigation that is historical or involves the use of information already in the public domain (such as information published in journals, newspapers or archives) should be assessed to determine whether it qualifies as human research. If such investigations are not human research, then neither ethics review nor a decision to provide an exemption from review is required.

Oversight of ethics review

19. *[revised 5.1.10]* Institutions should ensure that all review pathways and the criteria that are used for determining the appropriate pathway are clear, transparent and published so that researchers can submit their research proposals as efficiently as possible.

20. *[new]* Institutions should clearly publicise their policy for access by non-affiliated researchers to their HREC or other ethics review processes.

21. *[new]* Institutions should clearly publicise their policy and criteria for acceptance, or non-acceptance, of ethics review that is conducted external to the institution (see Chapter 5.5).

22. *[new]* Institutions should have standard operating procedures for overseeing the activity of their HREC and any other ethics review processes that they use.

23. *[5.1.13]* Institutions should regularly assess all of their ethics 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 the National Statement.

24. *[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.

25. *[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 that their criteria require, and
- b. research is being exempted from review only in accordance with the criteria set out in 5.1.X.

Establishment and composition of HRECs and other ethics review bodies

26. *[revised 5.1.26]* One or more institutions can individually or jointly establish an HREC.
27. *[revised 5.1.26]* Institutions that establish an HREC are responsible for adequately resourcing and maintaining it, including providing sufficient administrative support.
28. *[revised 5.1.25, 5.1.26 & 5.1.28]* An institution is responsible for ensuring that its HREC operates in accordance with this National Statement. This includes being satisfied that:
- a. the requirements for ethics review have been met (see X.X.X);
 - b. members have been properly selected and appointed (see membership requirements at 5.1.X–5.1.X);
 - c. members have or will undertake:
 - i. appropriate induction, which could include mentoring by an experienced HREC member; and
 - ii. continuing education;
 - d. review processes and procedures do not cause unnecessary delay;
 - e. committee decisions are transparent, consistent, and promptly communicated (see 5.2.X–5.2.X);
 - f. actual and potential conflicts of interest that may affect research and its review are identified and managed (see Chapter 5.6: Disclosure of interests and management of conflicts of interest);
 - g. good communication between the institution/s, the HREC and researchers is promoted (see 5.2.X to 5.2.X);
 - h. any fees that are charged for HREC review do not discourage research the institution has an obligation to support; and
 - i. the workload of the HREC does not compromise the quality and timeliness of ethics review.
29. *[new]* Institutions that establish other ethics review bodies to review minimal risk research should ensure that they are adequately resourced and maintained.
30. *[new]* Institutions should be satisfied that these review bodies meet the following requirements, as relevant:
- a. members have the experience and expertise that is relevant to research proposals to be considered by the review body;
 - b. review processes and procedures do not cause unnecessary delay;
 - c. committee decisions are transparent, consistent, and promptly communicated (see 5.2.X–5.2.X); and
 - d. the workload of the review body does not compromise the quality and timeliness of review.

Terms of reference

31. *[revised 5.1.27]* When establishing an HREC, an institution must set out and publicise its terms of reference, including:

- a. the scope of its responsibilities for ethics review;
- b. its relationship to other processes of review of research, including sub-committees and ethics review processes for research with minimal risk;
- c. whether, and under what conditions, the HREC will review applications from researchers that are not affiliated with the institution;
- d. *[revised 5.1.37(j)]* its mechanisms for accountability and reporting;
- e. the categories of all members appointed;
- f. details of remuneration, if any, for members; and
- g. *[revised 5.1.37(s)]* its schedule of fees charged, if any, for ethics review.

Minimum membership of an HREC

32. *[revised 5.1.30]* The minimum membership of an HREC is eight and must include the following categories:
- 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. two people, who have no affiliation with the institution and do not typically engage in medical, scientific, legal or academic work, who bring a broader community perspective;
 - c. a person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;
 - d. a person who performs a pastoral care role in a community, for example, a member of an Aboriginal and/or Torres Strait Islander community, a minister of religion, a chaplain, or a person involved in social support or mentoring services;
 - e. a lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or other matters; and
 - f. 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 from an established pool of inducted members with relevant expertise.
33. *[revised 5.1.31]* No individual may represent more than one of the categories listed in paragraph 5.1.X at any individual meeting, but may fill a different category at a separate meeting, so long as all minimum membership categories are represented at each meeting (see 5.2.X).
34. *[new]* Institutions may designate a member to carry out the duties of the chairperson when the appointed chair is not available (i.e. a deputy chair). When this member is acting as chair, reasonable efforts should be made to ensure that the minimum membership category filled by this member, if any, is filled by another HREC member. Where there is less than full attendance of the minimum membership at the meeting, see 5.2.X.

Additional members and pools for HRECs

35. *[revised 5.1.31]* Institutions may appoint members who are additional to the eight minimum members set out in 5.1.XX. These members may also represent minimum membership categories (for example, an additional lay person, lawyer or researcher) or have experience or expertise relevant to the work of the committee.
36. *[revised 5.1.31]* Institutions are encouraged to establish a pool of appointed HREC members. These members may attend meetings as needed to:

- a. meet the minimum membership requirements at 5.x.x, and/or
- b. provide experience or expertise relevant to the work of the HREC.

37. *[5.1.32]* Wherever possible one or more of the members listed in 5.1.X should be experienced in reflecting on and analysing ethical decision-making.

Diversity and expertise

38. *[revised 5.1.29]* As far as is practicable, institutions that establish HRECs should ensure that:

- a. the HREC membership includes gender diversity, and
- b. at least one third of those attending each meeting are from outside of the institution.

39. *[new]* As far as is practicable, any other ethics review body established by an institution should also include gender diversity among its members.

40. *[revised 5.1.33]* The institution should ensure that its ethics review bodies have access to the expertise necessary to enable it to properly review the research that it considers. This may necessitate going outside of the review body's membership. Areas of expertise that may be necessary for individual research projects could include:

- a. individuals with specialised scientific or scholarly expertise (including research methods);
- b. individuals with specialised technical expertise, such as statisticians or data security, storage and safety specialists;
- c. individuals with expertise related to participant groups, such as Aboriginal and Torres Strait Islander peoples or people living with a disability; and
- d. individuals with expertise related to research contexts, such as clinical or community care
- e. *[revised 5.2.19]* participant advocates

Appointment of HREC members

41. *[5.1.34]* 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.

42. *[revised 5.1.35]* Members should be appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organisation, department, group or opinion. Individuals that represent the institution (i.e. ex officio) may attend HREC meetings as observers, but are not to be appointed as members or be involved in the deliberations or decision making of the HREC.

43. *[revised 5.1.36 & 5.1.9]* Members should be provided with a formal notice of appointment that specifies:

- a. their responsibilities related to membership, including participation, training, confidentiality and disclosure of interests (see 5.2.X-5.2.X);
- b. the category of membership that they will represent at meetings;
- c. their term of appointment;
- d. any remuneration or other benefits with which they will be provided;
- e. that they are assured legal protection for any liabilities that may arise in the course of the bona fide conduct of their duties as reviewers of research.

Other responsibilities

44. *[new]* An institution's research governance responsibility includes providing and promoting a research culture that reflects the core values of research integrity, collaboration and collegiality and facilitating an environment where the design and planning of research is supported and valued.
45. *[revised 5.1.2]* Institutions should ensure that those conducting human research over which it has oversight responsibility:
 - a. are either adequately experienced and qualified for the roles and functions that they plan to perform, or are supervised by those who are;
 - b. understand the need to assess risks to their own safety and that of participants; and
 - c. are aware that they are free to withdraw from research on conscientious grounds.
46. *[revised 5.1.38]* Institutions must be satisfied that sponsors of research for which indemnity, insurance and compensation arrangements are required have arrangements in place that comply with applicable regulatory requirements.
47. *[5.1.39]* Institutions must also have arrangements in place to compensate participants for harm resulting from negligence in research.

Chapter 5.2: Responsibilities of HRECs and other ethics review bodies

INTRODUCTION

[new introduction] Oversight of research is an institutional responsibility. Most human research requires some form of ethics review. This review may be conducted by an HREC or other review body or process and may result in approval, re-consideration of a proposal at a later date, a decision not to approve the research or a decision to refer the proposal to a different review pathway.

By itself, ethics approval of research does not enable research to proceed. Research must also be authorised by one or more institutions or another body with responsibility for oversight of the research. The responsibility for the authorisation of research is an institutional responsibility and should take into account, but not re-review, any issues raised during the ethics review of the research proposal.

The concept of 'review by an HREC' may encompass review by all members of an HREC, all minimum members (see 5.1.X) or a delegated review, provided that the delegation is consistent with the National Statement and processes authorised by the institution overseeing the HREC. Authorisation of any delegation of review should include clarification of whether the full membership of the HREC must approve the research after delegated review is completed and whether this approval process permits further consideration by the HREC or is equivalent to a ratification process.

Where required, ethics review and approval must be obtained prior to the commencement of the research. Retrospective ethics approval of research is not supported by the National Statement.

Varying processes may be used for the review and approval of project extensions, amendments, progress reports and renewal of project approval. Appropriate processes depend on the nature of the original project and any proposed changes, but any process authorised by an institution for these purposes must prioritise the safety and well-being of participants, researchers and/or the community.

GUIDELINES

Ethics review body procedures

Standard operating procedures

48. *[revised 5.1.37]* An HREC must ensure that it documents, implements and publicises standard operating procedures that promote good ethics review, including:
- a. frequency of meetings;
 - b. attendance at meetings;
 - c. conduct of meetings;
 - d. preparation of agendas and minutes;
 - e. timely distribution of papers to members before meetings;
 - f. timely consideration of applications;
 - g. methods of deliberation and decision making;
 - h. processes, if any, for reviewing applications from unaffiliated or international researchers;
 - i. disclosure of interests and management of conflicts of interest (see paragraphs 5.X.X to 5.X.X);
 - j. appropriate confidentiality of the content of applications and the deliberations of review bodies;
 - k. prompt notification of decisions to researchers;

- l. communicating with researchers, including face to face, by telephone and in writing, (including available forms of electronic communication) (see paragraphs 5.2.X to 5.2.X);
 - m. record keeping (see paragraphs 5.2.X to 5.2.X)
 - n. monitoring of approved research (see paragraphs 5.X.X to 5.X.X)
 - o. reporting and handling of adverse events
 - p. receiving and handling of complaints (see paragraphs 5.X.X to 5.X.X)
 - q. advising the institution/s of decisions to withdraw ethics approval of a research project (see paragraphs 5.X.X to 5.X.X); and
 - r. attendance of people other than members (see paragraph 5.x.x) at meetings.
49. *[new]* Other ethics review bodies should also ensure that they have good working procedures that are documented and implemented. These should include the relevant procedures from paragraph 5.X.X and paragraphs 5.X.X to 5.X.X.

Meeting procedures for HRECs

50. *[revised 5.2.30]* As far as is practicable, each HREC meeting should be arranged to enable attendance of all appointed members, either in person or via available technology, for example videoconference.
51. *[revised 5.2.30 & 5.2.31]* Meeting papers should be provided enough in advance to enable members to be fully informed. Decisions by an HREC about whether a research proposal meets the requirements of the National Statement should be informed by an exchange of opinions from all members of the HREC. Ideally, this exchange should take place at a meeting with all those members physically present or participating using available technology.
52. *[revised 5.2.32]* Where there is less than full attendance of the minimum members at a meeting, the Chairperson must be satisfied that the views of the minimum members who are not present have been received and considered before a decision is made.
53. *[revised 5.2.20, 5.2.21]* An HREC may:
 - a. invite researcher/s, and researchers may request, to be present for discussion of their proposed research;
 - b. seek advice from external experts to help in considering a research proposal. Such experts should be bound by the same confidentiality requirements as the HREC members. Any interests they may have should be disclosed and any conflicts of interest identified and managed appropriately (see Chapter 5.6);
 - c. *[new]* invite observers to attend meetings. Any invited observers should not be involved in deliberations or decision making, but are still bound by the same confidentiality and disclosure of interests requirements as HREC members.

Making decisions

54. *[revised 5.2.23 & 5.2.24]* A review body may approve, request modification of, or reject a research proposal on ethical grounds. If rejecting a research proposal, a review body should provide the rationale for its decision, including citing the provisions of the National Statement that underpin its decision, if relevant.

55. *[revised 5.2.33]* A review body should try to reach decisions by general agreement or consensus. Voting is neither required nor prohibited. Some decisions may not be unanimous and, where requested by a dissenting member, a dissent should be recorded in the minutes of the meeting.

Communication with researchers and sponsors of research

56. *[revised 5.2.14]* Good ethics review requires open communication between review bodies and researchers, and a shared commitment to a constructive review process. Ways to facilitate this shared commitment include:
- a. providing access by researchers to review bodies and their support staff; and
 - b. promoting awareness of and training related to the National Statement among researchers.
57. *[revised 5.2.15]* Misunderstandings can often arise when communication is only in written form. Review bodies should encourage informal communication with researchers, and should consider holding face-to-face meetings to resolve issues about research proposals that may be difficult to resolve through other means.
58. *[revised 5.2.24 & 5.2.28]* The review body must clearly communicate its decision on a research proposal to the researcher/s:
- a. Where a proposal is approved or rejected, communication must be in writing (which may include electronic formats) and should include an explicit statement that the proposal meets or did not meet the requirements of the National Statement.
 - b. Where modifications are requested, communication may be written or, where appropriate, informal; however, a record should be kept of any informal communication.
59. *[revised 5.2.22]* Communication between a review body and a research sponsor is not prohibited, but should be restricted so that it does not inappropriately influence the review of any relevant research proposals.

Documentation and record keeping

60. *[revised 5.2.25]* All documents and other material used in recruiting potential research participants to a specific research project, including advertisements, letters of invitation and information sheets and consent forms, should be approved by the review body. If general promotional material (e.g. posters or websites encouraging participation in clinical trial research) is not related exclusively to a specific project, then ethics review is not required.
61. *[revised 5.2.25 & 5.2.27]* Documents intended for use in the conduct of a research project, including but not limited to protocols or project descriptions, questionnaires, surveys, scripts and case report forms should be approved by the review body.
62. *[new]* Documentation submitted in support of any amendment of a research project should be approved by the review body directly or by delegation, as appropriate.
63. *[new]* Forms used to apply for ethics review are not project documentation and do not need to be approved, as such, by the review body, unless there is no other documentation supporting the application.

64. *[revised 5.2.26]* A review body should maintain a record of all research proposals received and reviewed, including, but not limited to the:
- a. name/s of the institution/s to which the approval is provided;
 - b. project identification number/s;
 - c. title of the project;
 - d. name of the principal researcher/s;
 - e. correspondence between the review body and the researcher about the review/s;
 - f. advice of approval or rejection of the proposal and any amendments to the project;
 - g. terms and conditions, if any, of the approval of any proposal or amendment;
 - h. duration of the approval;
 - i. proposed date of completion of the project;
 - j. name of any other review body whose opinion was considered;
 - k. mechanisms to be used to monitor the conduct of the research; and
 - l. record of assessments required by the Commonwealth, State or Territory legislation or guidelines relating to privacy of personal or health information.
65. *[revised 5.2.27]* A review body should retain a copy of all applications for ethics review, all approved project documentation and any relevant correspondence.
66. *[new]* Review bodies should retain records in accordance with the requirements of relevant Commonwealth and state or territory legislation and guidelines.

Review body member responsibilities

67. *[revised 5.2.2]* Each member of a review body is responsible for deciding whether, in their judgement, a research proposal meets the requirements of this National Statement and is ethically acceptable.
68. *[revised 5.2.3]* To fulfil that responsibility, each member of a review body should:
- a. undertake any induction training or process provided by the institution or review body;
 - b. become familiar with this National Statement, and consult other guidelines and information relevant to the review of specific research proposals;
 - c. 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
 - d. attend continuing education or training programs in research ethics at least every three years, or as provided by the institution or review body.
69. *[new]* Members of a review body should be aware of and respect any protocols related to confidentiality in the performance of their role(s). These may be relevant to interactions with other members of the review body, with administrators or with researchers, or to review of research proposals or any discussion occurring at a meeting or online about matters within the remit of the review body.
70. *[revised 5.2.4]* Members of a review body should disclose to its Chair and administrator(s) any interests that may constitute an 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 Chapter 5.6).

[new chapter] Chapter 5.3: Responsibilities of researchers**INTRODUCTION**

[new introduction] Researchers bear significant responsibility for the ethical conduct of research, beginning with the design of the research and extending through the ethics review submission process; recruitment of participants; project activity; data analysis; data storage and security; monitoring; communication, publication and dissemination of the results and outcomes of the research; as well as follow-up with participants, if required. The researcher is responsible to their institution, any sponsors or funders of the research, participants and, in some research, to regulators or other entities who have a formal role in the oversight of research.

GUIDELINES

71. *[revised 5.2.5]* In each research proposal, the researcher/s should demonstrate that the research has merit and integrity and reflects the values of justice, beneficence and respect for human beings (see Section 1).
72. *[5.2.6]* For relevant health research, researchers should show that the research meets the requirements of the CPMP/ICH Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ISO 14155 Clinical Investigation of Medical Devices, the World Health Organization International Clinical Trials Registry Platform and the TGA.
73. *[revised 5.2.7 & new]* Research proposals should be clear and comprehensive, and written in lay language. Researchers should be aware that the submission of poor quality proposals for review may delay the review, ethical approval and/or institutional authorisation process, with consequent impact on potential participants in the research or the community.
74. *[revised 5.2.17]* Researchers should present information about the research to participants in ways that help them make good choices about their participation, and support them in those decisions and in their participation. Researchers should consider:
 - a. whether the information is best communicated through speech, writing, visually or in some other way, or a combination of these;
 - b. the need for accurate and reliable translation (written and/or oral) of the information into a participant's first language or dialect;
 - c. the participant's cultural background and its potential effects on the communication process;
 - d. the participant's educational background and level of literacy, numeracy and understanding of scientific and academic concepts, if known;
 - e. the participant's age and level of maturity; and
 - f. any visual, hearing or communication impairment with which the participant is living.
75. *[revised 5.2.8]* A researcher should disclose the amount and sources or potential sources of funding for the research to the review body and, where appropriate, the participants. This information may include financial support, in-kind support, per capita payments or other payments or incentives provided by any entity supporting the research.

76. *[revised 5.2.9]* A researcher developing or designing a research proposal involving two or more institutions should inform each of them of the institutions involved in the research at an early stage in the process.
77. *[revised 5.2.10]* A researcher should keep an auditable record of any research they are undertaking that is exempted from ethics review in accordance with X.X.X.
78. *[revised 5.2.13]* For researcher responsibilities related to monitoring, see Chapter 5.4.

Disclosure of interests

79. *[revised 5.2.11]* A researcher should disclose to the review body any interests that may constitute an actual or potential conflict of interest, including any financial or other interest or affiliation that bears on the research (see Chapter 5.6). Where applicable, this disclosure should specify any business, financial or other relevant association between a researcher and the developer, manufacturer or supplier of a drug, device or other product of potential commercial value to be used in the research. A researcher should disclose to the review body any restrictions on publication or dissemination of research findings.
80. *[revised 5.2.12]* When reporting the research, a researcher should again disclose any interests that may constitute an actual or potential conflict of interest, including any financial or other interest or affiliation that bears on the research.

Chapter 5.4: Monitoring

INTRODUCTION

[revised introduction] Those responsible for the oversight of research include researchers, institutions, reviewing HRECs and sponsors of research, and any expert committees that may be established to assist any of these parties in the fulfilment of their responsibilities. For some types of complex research, regulatory agencies may also be involved in monitoring activities.

Primary responsibility for ensuring that research is reliably monitored lies with the institution/s under whose auspices the research is conducted. Within an institution, the delegation of monitoring responsibilities should be consistent with that institution's research governance framework and may include delegating responsibility for discrete aspects of monitoring to oversight committees, experts within the organisation or administrative staff. Delegations of this kind are necessary and should be supported.

Traditionally, it has been common practice for an institution to delegate significant monitoring responsibilities to the institution's HREC, based on the HREC's knowledge of the project gained from having conducted a review of the project. However, where research that will take place at multiple sites has been reviewed by only one HREC, the HRECs of the other institutions participating in the project no longer have knowledge of the project. In such cases, only the reviewing HREC can take on those elements of monitoring a research project that are commonly attributed to HRECs. The outcome is that HRECs that do not conduct a substantive review of a research project cannot and should not have a monitoring role with respect to that project and cannot accept the delegation of responsibility from an institution to perform such a role.

For more information on monitoring of research and its place in the governance of research, there are additional resources available from NHMRC and the Commonwealth of Australia Department of Health.

There are a wide variety of mechanisms and strategies that can be employed to monitor research. These mechanisms include the review or conduct of:

- reports from researchers, received at least annually;
- reports from independent committees or groups (such as a data and safety monitoring board (DSMB));
- adverse event and other safety reports;
- amendments to the research project submitted by researchers;
- interviews or meetings with researchers;
- reports of internal project audits;
- audits of research documentation conducted by institutions or review bodies;
- random or targeted inspections by sponsors, collaborative research organisations or regulators that assess research sites, data integrity and security, or project documentation and records;
- reports commissioned by the institution from an independent monitor;
- interviews with research participants or other forms of feedback from participants; and
- final project reports and published results or notification of publication or dissemination of outcomes.

Institutions should clarify which monitoring mechanisms and strategies they will employ and maintain appropriate records of the monitoring that they do.

Sponsors of clinical trial research also have significant monitoring and reporting responsibilities and allocation of monitoring responsibilities amongst sponsors, institutions, review bodies and researchers should be clear to all of these for each research project. In addition, an institution may function as the sponsor of the research or as the coordinator of a multi-centre research project and/or as the host for the body conducting the ethics review, as well as being a participating site (or group of sites). Accordingly, institutions should be clear and transparent about which of their monitoring responsibilities are associated with which role.

GUIDELINES

Monitoring approved research

81. *[revised 5.5.1]* Each institution has ultimate responsibility for ensuring, via its research governance arrangements, that all its authorised research is monitored.
82. *[5.5.2]* Monitoring arrangements should be commensurate with the risk, size and complexity of the research.
83. *[5.5.3]* For each clinical trial, institutions and review bodies should ensure that there are appropriate mechanisms for safety monitoring and reporting, including standard safety reporting. The use of a Data and Safety Monitoring Board (DSMB) or (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 is recommended and may be required. Researchers should refer to other published NHMRC guidance addressing these matters.
84. *[5.5.4]* 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.
85. *[5.5.5]* 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.
86. *[new]* The continuation of ethics approval of research must be on the condition that the researchers:
 - a. conduct the research in compliance with the approved protocol or project description;
 - b. submit for approval any amendments to the project, including but not limited to amendments that:
 - i. are proposed or undertaken in order to eliminate immediate risks to participants; and
 - ii. may increase the risks to participants; or significantly affect the conduct of the research.
87. *[revised 5.5.6]* The continuation of ethics approval of clinical trial research must be on the condition that the researchers also:

- a. provide reports of the progress of the trial and any safety reports or monitoring arrangements as indicated in NHMRC guidance and in accordance with the manner and form specified by the review body;
- b. inform the review body as soon as possible of any new safety information from other published or unpublished research that may have an impact on the continued ethical acceptability of the research or that may indicate the need for modification of the project;
 - i. for clinical trials with implantable medical devices, confirm the existence of, or establish, a system for enabling the tracking the participant, with consent, for the lifetime of the device.

Suspension of research or withdrawal of approval

88. *[revised 5.5.7]* 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 multiple ethics reviews have been conducted, it must be clearly established, before the research begins, how this information will be communicated.
89. *[revised 5.5.8]* Where a review body or institution finds reason to believe that continuance of a research project will compromise participants' welfare, it should immediately seek to establish whether ethics approval and/or authorisation for the project should be withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect.
90. *[5.5.9]* It may be unethical for a researcher to continue a clinical trial if:
 - a. there are or have been substantial deviations from the trial protocol;
 - b. adverse effects of unexpected type, severity, or frequency are encountered; or
 - c. as the trial progresses, the continuation of the trial would disadvantage some of the participants as determined by the researchers or others monitoring the trial.
91. *[revised 5.5.10]* Where ethics 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 to the satisfaction of the review body 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.
92. *[5.5.12]* In the light of reports received under 5.5.X and 5.5.X, review bodies may require researchers to amend research procedures to protect participants. If a review body determines that such changes cannot achieve that end, the review body may decline to grant an extension to project approval or decide to suspend the research in accordance with 5.5.X and 5.5.X – 5.5.X.

93. *[5.5.11]* If an institution or review body considers that urgent suspension of research is necessary before the process described in 5.5.X and 5.5.X is undertaken, the instruction to stop should come from the management of the institution.

Closure of an institution and/or review body

94. *[new]* If an institution and/or its review body intends to cease operating, the institution must notify all principal researchers of ongoing projects of the planned closure and work cooperatively with the researchers to ensure the transfer of current projects to another institution and/or review body for ongoing monitoring. This process must be completed prior to the planned closure.
95. *[new]* The institution remains responsible for monitoring all approved research until this responsibility is successfully transferred to another institution and/or review body.

Chapter 5.5: Minimising duplication of ethics review

INTRODUCTION

[revised introduction] Research that may generate duplication of ethics review includes:

- research that will be conducted at more than one institution, either by the same or different researchers;
- research that will be conducted jointly by researchers affiliated with different institutions, either within Australia or in two or more countries;
- research that will be conducted at one institution by a researcher affiliated with another institution, for example, a university-based researcher conducting research at a hospital or a researcher affiliated with an overseas institution conducting research in an Australian institution;
- research approved at one institution and transferred to another, for example, when a researcher changes their institutional affiliation; and
- any other research for which more than one institution has responsibility for ethics review and authorisation.

Duplication of ethics review can also be associated with research that is conducted in more than one research sector, for example:

- research conducted within both publicly funded and private institutions;
- research conducted at both hospitals and universities; or
- research conducted within an institution and in one or more communities.

The unnecessary duplication of ethics review is unethical insofar as it delays the commencement of research that may be directly or indirectly beneficial to the Australian community and wastes valuable resources. Furthermore, there is no requirement that research conducted in an institution or by researchers affiliated with that institution must be ethically reviewed by that institution.

The National Statement supports the minimisation of any unnecessary duplication of ethics review both within and across research sectors. This support extends to research that will be conducted in more than one Australian jurisdiction or across national boundaries.

Ethics review and approval is not equivalent to and does not obviate the need for authorisation of research by institutions with a responsibility to oversee the research. Nevertheless, the National Statement also supports the minimisation of any unnecessary duplication of processes or assessments that may be used in the authorisation of multicentre research.

GUIDELINES

96. *[revised 5.3.1]* Wherever more than one institution has a responsibility under research governance to ensure that ethics review of a human research project has taken place (see paragraph 5.1.X), each institution has the further responsibility to adopt a review or authorisation process that eliminates any unnecessary duplication of ethics review.
97. *[new]* Institutions that will serve as individual sites for a multicentre research project should make every effort to avoid multiple ethics reviews of the same research project. This principle applies to all types of research and to both research that will be reviewed by an HREC and research that will be reviewed using a process that is appropriate for minimal risk research (see 5.1.X).

98. *[revised 5.3.3]* When deciding to rely on the ethics review of an HREC or other ethics review body over which it does not exercise oversight, institutions:
- a. should provide any relevant information on local circumstances to the reviewing body;
 - b. should provide clear information to researchers on the institutional processes for authorisation that will be required;
 - c. should clarify and/or negotiate with the reviewing body's institution, the reviewing body and the researchers, the monitoring roles that will be the responsibility of each party for the project;
 - d. should not engage in supplementary scientific or technical review of the research, except as agreed to by the reviewing body; and
 - e. should adopt any other administrative processes that will support the decision to rely on external ethics review.
99. *[revised 5.3.4]* To facilitate the efficient ethics review of research, researchers must inform any reviewing body of:
- a. all other sites at which the research will be conducted;
 - b. any other body that will be considering ethical issues related to the research; and
 - c. any previous decisions to approve, re-consider or deny approval of the research by another review body in Australia or elsewhere.

Chapter 5.6: Disclosure of interests and management of conflicts of interest

INTRODUCTION

[revised introduction] Proper management of conflicts of interest in research requires the disclosure of all interests that are relevant, or could appear to be relevant, to proposed or ongoing research. Relevant interests may need to be disclosed to institutions, review bodies, funding bodies, research participants, publishers and journal editors, collaborators and the public.

Researchers, members of review bodies and institutions, themselves, may have interests that are relevant to individual research projects or research programs that may merit disclosure to some or all of these entities.

A conflict of interest exists in a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. In the context of research, it exists where a person's individual interests or responsibilities have the potential to influence the carrying out of their institutional role or professional obligations in research or an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

While a conflict may relate to financial interests, it can also relate to personal, familial, professional or organisational benefits or advantages that depend significantly on or could unduly influence research outcomes.

The perception that a conflict of interest exists is a serious matter and can raise concerns about the integrity of individuals or the management practices of the institution, potentially undermining community trust in research.

Whether an activity or an affiliation, association or relationship gives rise to a conflict of interest is a determination to be made by the appropriate decision maker. In making this determination, it should be recognised that having multiple interests does not necessarily constitute a conflict of interest and that having a conflict of interest does not, in itself, imply improper motivation or individual wrongdoing.

Further information on disclosure of interests and management of conflicts of interest is available in material supporting the [Australian Code for the Responsible Conduct of Research](#).

GUIDELINES

100. *[revised 5.4.1]* Institutions should establish transparent processes that facilitate the disclosure of interests and the identification and management of actual and potential conflicts of interest involving:
 - a. the institution itself;
 - b. ethics review bodies, their members or advisors; or
 - c. researchers.

101. *[revised 5.4.2 & 5.4.4]* An institution with an established conflict of interest bearing on research should inform relevant ethics review bodies about the conflict. Correspondingly, where an ethics review body becomes aware that there may be a conflict of interest involving the institution, the review body should notify the institution.

102. *[revised 5.4.5]* An ethics review body should require its members, and any experts whose advice it seeks, to disclose any interest that may constitute a conflict of interest that is related to the research under review, including any:
- a. personal involvement or participation in the research;
 - b. financial or other interest or affiliation; or
 - c. involvement in competing research.
103. *[revised 5.4.5]* Ethics review bodies should adopt measures to identify and manage conflicts of interest involving their members. These measures should be tailored to the individual circumstances and may include requiring that:
- a. the information be disclosed to researchers; or
 - b. the member absent themselves from a meeting or from any deliberations or decision making about the research.
104. *[new]* Researchers should disclose any interest that may constitute a conflict of interest that is related to their research proposal, including any:
- a. financial or other interest or affiliation; or
 - b. involvement in competing research.
105. *[revised 5.4.3]* Ethics review bodies should adopt measures to identify and manage conflicts of interest involving researchers. These should be tailored to the individual circumstances and may include one or more of the following measures:
- a. requiring that the information be disclosed to research participants;
 - b. requiring that the information be disclosed in any presentation or publication of the research results or outcomes;
 - c. requiring that the researcher absent themselves from any deliberations or decision making about the research;
 - d. requiring that the researcher plays a different or reduced role in some or all of the research, including not being involved in recruitment or making the initial approach to participants;
 - e. involving an appropriate individual to oversee some or all of the research activity;
 - f. requiring the researcher to relinquish financial or other interests; or
 - g. requiring the researcher to withdraw from the conduct of the research.

Chapter 5.7: Complaints

INTRODUCTION

[revised introduction] Institutions may receive complaints about researchers or the conduct of research, or about the conduct of an HREC or other ethics review body. Complaints may be made by participants, researchers, staff of institutions, or others. All complaints should be handled promptly and sensitively.

The [Australian Code for the Responsible Conduct of Research](#) provides guidance to institutions on managing and investigating potential breaches of the Code. Where complaints about researchers or research raise the possibility of a breach of the Code, they should be dealt with under the recommended processes.

Complaints related to the review or approval of research should be directed to the Chair of the review body or appropriate institutional staff. It may be possible for a complainant to request re-consideration of a decision related to their research proposal. If an institution is concerned that the integrity of any review body that it maintains has been compromised, the institution can consider referring its concerns to an independent assessor.

GUIDELINES

106. *[revised 5.6.1 & 5.6.7]* To handle complaints about researchers or the conduct of research, institutions should:
 - a. identify a person, accessible to participants, to receive these complaints; and
 - b. establish and publicise procedures for receiving, handling and seeking to resolve such complaints.
107. *[revised 5.6.2 & 5.6.3]* Where such complaints raise the possibility of a breach of the standards governing the conduct of research, they should be handled in accordance with the processes set out in the [Australian Code for the Responsible Conduct of Research](#).
108. *[revised 5.6.4 & 5.6.7]* Institutions should also establish and publicise procedures for receiving, handling and seeking to resolve complaints about the conduct of review bodies in reviewing research proposals.
109. *[revised 5.6.5 & 5.6.6]* These complaints-handling procedures should include:
 - a. methods for communicating with the review body, including an identified person or position that is accessible to the complainant and can receive the complaint;
 - b. where the complaint cannot be readily resolved by communication between the complainant and the review body that is the subject of the complaint, institutions may choose to refer the complaint to an independent assessor.

Chapter 5.8: Accountability

INTRODUCTION

[revised introduction] Responsibility for the ethical design, review, conduct and monitoring of human research is exercised by different parties at different levels of an institution (such as researchers, ethics review bodies and administrative and executive officers) and, in some instances, by government agencies or organisations that set international standards.

The line of accountability for these responsibilities varies depending on the nature of the research but often runs:

- from researchers to review bodies and institutions;
- from review bodies and institutions to funding bodies and/or government agencies, including regulators;
- from sponsors of research to government agencies, including regulators; and
- from governments to the Australian public.

Typically, this accountability involves reporting from one level to the next.

GUIDELINES

110. *[revised 5.7.1 & 5.7.2]* Researchers, review bodies and institutions have responsibilities for the ethical design, conduct and monitoring of research. The measures of accountability by which they demonstrate, fulfilment of those responsibilities are described in other chapters of Section 5.
111. *[revised 5.7.1 & 5.7.3]* Researchers and institutions have responsibilities that are set out in the Australian Code for the Responsible Conduct of Research. Additional guidance on fulfilment of these responsibilities is provided in a set of guides that support the Code.
112. *[revised 5.7.5]* Institutions that are in receipt of NHMRC or ARC research funding, or intend to remain eligible for it, must register their HREC with NHMRC.
113. *[revised 5.7.6]* NHMRC requires that institutions attest annually, in writing, that their research governance and ethical oversight processes remain compliant with the National Statement and the Code.
114. *[revised 5.7.4]* Institutions shall, on reasonable request, provide information about their ethics review processes to NHMRC, including via annual reporting on the activity of its HREC.