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National Health and Medical Research Council

N|H|M|R|C

Research Governance Handbook:
Guidance for the national approach
to single ethical review

December 2011

WORKING TO BUILD A HEALTHY AUSTRALIA

Introductory comment

BACKGROUND

A critical element of the Harmonisation of Multi-centre Ethical Review (HoMER) initiative[1] is the need for research governance to be understood as comprising distinct elements ranging from the consideration of budgets and insurance, to the management and conduct of scientific and ethics review. In recent years, the concept of research governance has grown from being considered an ancillary responsibility of the Human Research Ethics Committee (HREC) to one that is understood as the responsibility of the institution where the research is being conducted.

While this conceptual change and the resulting changes in roles and responsibilities may still need further refinement, the requirements of the HoMER initiative have highlighted the need to ensure that the different components of research governance are well understood.

Although research governance arrangements inevitably vary amongst institutions, in order for a national approach to single ethical review to be workable there is a need to establish consistency in the area of research governance, particularly among institutions that have had their ethical review processes certified under the HoMER initiative. The process of fostering consistency may take the form of encouraging standardisation of the site assessment processes used to support authorisation of a research project at a research site, to developing a consensus about the components of research governance, and how they are structured and allocated in accordance with an overall governance framework.

PURPOSE OF THIS DOCUMENT

The purpose of this document is to articulate best practice in the governance of multi-centre human research as part of the national approach to single ethical review. The document guides the reader through the components of a research governance framework for multi-centre human research and describes the roles and responsibilities of key stakeholders within the framework.

An institution's responsibilities in the governance of research are described in the:

* *National Health and Medical Research Council (NHMRC)/Australian Research Council (ARC)/Universities Australia Australian Code for the Responsible Conduct of Research (2007)* (the Code) http://www.nhmrc.gov.au/publications/synopses/r39syn_intro.htm; and
* *NHMRC/ARC/Australian Vice Chancellors' Committee National Statement on Ethical Conduct in Human Research (2007)* (the National Statement) http://www.nhmrc.gov.au/ guidelines/ethics/human_research/index.htm.

Professional judgement is involved in the interpretation of this guidance document as no single document adequately captures the full range of legislation, standards and guidelines that apply to human research. Good practice in research governance depends on those with research governance responsibility being appropriately skilled and experienced and working in an environment that enables them to use their professional judgement effectively.

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1   The glossary of terms used in HoMER project documentation is found at
     www.hrep.nhmrc.gov.au/national-approach/glossary.

Introductory comment

This document does not replace existing national guidance documents or override any jurisdictional administrative and/or statutory requirements. It relates the national guidance to the internal activities of an institution conducting multi-centre human research.

The issues around research relating to specific population groups, such as Aboriginal and Torres Strait Islander Research and research in remote communities are not discussed in this Handbook. As such, adherence to this Research Governance Handbook alone is not sufficient for research involving Aboriginal and Torres Strait Islander peoples. A separate body of work is underway as part of the HoMER initiative relating to research involving Aboriginal and Torres Strait Islander communities. The following NHMRC publications should also be referred to:

• *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003), http://www.nhmrc.gov.au/guidelines/publications/e52; and
• *Statement on Consumer and Community Participation in Health and Medical Research* (NHMRC and Consumers' Health Forum of Australia Inc, 2002), http://www.nhmrc.gov.au/guidelines/publications/r22-r23-r33-r34.

HOW TO USE THIS DOCUMENT

This document may be of greatest assistance to institutional managers, administrators supporting governance activities and their colleagues supporting research ethics. It aims to provide investigators engaged in multi-centre human research with a better understanding of governance activities that the institution must address before, during and after research has commenced, as well as how the relationship between the Coordinating Principal Investigator (CPI) and the ethical review process supports these activities.

An institution should have specific policies and procedures in place relating to its governance of all research, whether multi-centre or single centre. This document provides a reference against which an institution can compare their internal administrative practices, recognising that research governance for single centre research has a high degree of overlap with multi-centre human research governance. This document is recommending best practice in this area and institutions are encouraged to regularly review their research governance policies, particularly if they are interested in applying for certification under the HoMER initiative.

In this document, research governance is discussed as an institutional responsibility. Nevertheless, it is recognised that a critical component of research governance, the authorisation of the commencement of a research project, may reside at a higher level such as a health district or other government body. The term institution is used broadly to mean a research institution, organisation or, in certain cases, individuals or jurisdictions (States and Territories of Australia), either in the public or private sector, under whose authority research is conducted.

Further information about jurisdictional level research governance practices in public health organisations is outlined in Appendix A.

Contents

I. Research governance framework

Research must be 'governed' at all stages of a project. The governance of research will ensure that its delivery meets its objectives and conforms to relevant institutional, jurisdictional and national standards and applicable laws.

Research governance implements the principles, requirements and standards of research. It addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice.

Institutions should ensure that their procedures and policies and other documents that guide good research governance, conduct and management, are open, transparent and available to members of the community.

The combination of all institutional activities that govern research, irrespective of who is responsible for any one activity, is known as an institution's research governance framework.

An institution's research governance framework defines the way all staff involved in research share responsibility and accountability for the institution's research being conducted according to appropriate regulatory, ethical and scientific standards and within the levels of acceptable institutional risk.

Sponsors of research have parallel responsibilities to properly govern research with which they are associated. These obligations are independent of the institution's research governance framework and are not addressed in this document.

A well-developed research governance framework ensures that:

- research is promoted as a valued activity in the institution;
- activities that the institution offers that will promote good research practice (e.g. appropriate training and education of staff in good and ethical research practice) are described and promoted;
- responsibilities and accountabilities for individuals and groups are understood, enacted and maintained;
- processes used are appropriate to the institution's research environment and sufficiently adaptable to recognise differences in the relative risk of certain types of research (e.g. interventional research in contrast to observational research);
- research governance activities are monitored and evaluated and the framework is modified as appropriate;
- the self-regulation of all contributors to research upon which the preservation of research integrity depends is affirmed and can be shown to be practiced;
- the framework is accessible to all relevant parties;
- the rights and reputations of researchers and research participants are respected and conflicts of interest are declared; and
- the outcomes of research are communicated responsibly.

MULTI-CENTRE RESEARCH GOVERNANCE THAT HAS UNDERGONE SINGLE ETHICAL REVIEW

The ethical review upon which the institution relies and the responsibilities for managing and monitoring multi-centre human research may involve external groups or individuals operating under contract or in another arrangement (e.g. provision of indemnity) with the institution carrying out the research. While an institution's research governance framework applies to all research, whether multi-centre or not, there are particular responsibilities that need to be set out in a research governance framework for multi-centre human research projects that have undergone a single ethical review.

Although some research governance activities supporting collaborative research may be coordinated across centres (e.g. the application for a single ethical review), each institution remains responsible for authorising the commencement of research and for the appropriate governance of research activity at each institutional location where the research is carried out.

II. The relationship between research governance and ethical review

Ethical review and site assessment are two distinct processes relating to the ethical approval and institutional authorisation of research involving humans. They are both components of research governance.

As noted earlier, the concept of research governance has grown from being considered an ancillary responsibility of the Human Research Ethics Committee (HREC) to one that is the responsibility of the institution where the research is being conducted. This is because research governance encompasses both ensuring adequate ethical review and institutional considerations about undertaking research in the context of the institution's policies, strategic priorities, expertise, resources, contractual arrangements, financial issues and approach to risk management.

As indicated, research governance takes place via an institutional framework that, when followed, ensures that all research meets applicable legal, regulatory and institutional requirements, appropriate ethical and scientific standards and standards of quality, safety, privacy, risk management and financial management.

The ethical review of human research is undertaken by a properly constituted HREC, or for low risk research, possibly another ethical review body or process.[2] This review body assesses proposed research in the context of the rights, dignity and welfare of participants in research as well as ensuring that the research is scientifically sound and promotes good research.

The institutional consideration as to whether an individual research project is a good fit for the institution at the time it is proposed is the 'site assessment' process, sometimes known as 'research governance review'. This process takes into account the ethical review upon which the institution has chosen to rely, institution-specific considerations such as resources, budget, risk management, and applicable legal, regulatory, jurisdictional and other administrative requirements. The outcome of the site assessment is an institutional authorisation of a research project or a decision not to authorise a specific project.

However, there may be times when ethical consideration of a project by an HREC will draw on matters of relevance to the institution's research governance responsibilities and vice versa. For instance, a project's budget may have direct bearing on the ethical appropriateness of the project when insufficient financial resources compromise the scientific validity of the project or the burden on the participants.

Conversely, a project that an HREC has deemed ethically appropriate may be inconsistent with one or more institutional policies.

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2   Within the National Statement, an institution may implement an alternative process for reviewing the ethical acceptability of low risk or negligible risk research.

GENERAL REQUIREMENTS OF INSTITUTIONAL SITE ASSESSMENT AND PROJECT AUTHORISATION IN SATISFACTION OF ITS RESEARCH GOVERNANCE RESPONSIBILITIES

Before an institution can authorise the commencement of research, the relevant decision makers will consider the risks involved in conducting the research against the institution's levels of tolerated risk.

A range of information will be considered in the risk assessment; including (but not limited to) whether the research project has been ethically reviewed and approved. Ethical approval is a pre-requisite for research commencement; however, the institution may choose not to authorise ethically approved research because of other factors. Not withstanding this sequence, aspects of site assessment may take place in parallel with the ethical review process. This matter will be discussed in more detail below.

In addition to an HREC, other individuals or groups may provide advice to the institutional decision maker (and/or their delegate) in order for them to authorise the commencement of research. This may include individuals or groups with legal, financial, technical, scientific or intellectual property expertise or relevant institution-specific knowledge or information.

The decision maker, generally a senior officer (e.g. the Chief Executive Officer or Deputy Vice-Chancellor of Research, or equivalent State Public Health Officer) or their delegate, will weigh up the advice and information provided by all groups against the levels of acceptable risk, and the importance of the research to their institution, before authorising research. Institutional research governance officers have an important role to play in providing the decision maker with appropriate documentation and advice.

As a decision to authorise the commencement of research in an organisation takes into account the separate and distinct results of both the ethical review and the site assessment, it is best practice for the decision-maker to be a person in the institution who is not the Chair of the HREC. The National Statement states that the Chair of the HREC should be a person with suitable experience whose other responsibilities will not impair the HREC's capacity to carry out its obligations.[3]

Requirements specific to the national approach to single ethical review:

In the national approach to single ethical review, site assessment and project authorisation are the responsibility of each institution participating in a multi-centre human research project while ethical review is provided by only one HREC using certified ethical review processes.

Each institution collaborating in a multi-centre project utilising the outcome of a single ethical review must individually authorise the commencement of research at their institution. To avoid unnecessary delays in research commencing at all collaborating centres (and sites), each institution should consider relevant local matters prior to or in parallel with ethical review.

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3   The National Statement, Section 5.1.30.

II. The relationship between research governance and ethical review

It is recognised that institutions and jurisdictions will have established policies about undertaking site assessment in parallel with ethics review. It is recommended that as part of the national approach to single ethical review, institutions establish effective processes to facilitate parallel review.

It is helpful to consider project documentation related to site assessment as falling into three categories:

    (a) that which can be assessed independent of ethical review, such as evidence of research qualifications, supporting department approval forms, contracts, budgets and insurance and indemnity documents;

    (b) that which is subject to ethical review, but can be submitted prior to or in parallel with ethical review to enable independent assessment of other documentation, such as initial project application documents; and

    (c) that which can only be assessed subsequent to ethical approval, such as approved project application documents, fully signed regulatory documents and a certificate of ethical approval.

The site assessment process can be similarly divided into stages of review. Review of documentation that can be assessed independent of ethical review can be undertaken while the proposal is being considered by an HREC or earlier. Not doing so may unnecessarily delay the completion of the site assessment process and extend project authorisation timelines.

As evidence of HREC approval is a component of the site assessment process, authorisation of a research project cannot be given until HREC approval has been provided.

The HREC undertaking the single ethical review may be located at an institution participating in the multi-centre research, but this is not a requirement of the national approach to single ethical review.

Researchers should be aware of any specific State or Territory requirements and may choose to submit their research proposal to any HREC that uses certified ethical review processes.

The Chief Principal Investigator (CPI) is responsible for submitting the application for ethical review to the HREC and notifying the Principal Investigators (PIs) in each participating institution of the results of the HREC review.

Similarly, the authorisation of research at each institution must be communicated by each PI to the CPI.

Likewise, if the HREC that approved the project withdraws its approval at any stage once the research has commenced, then the HREC must notify the CPI. It is the responsibility of the CPI to notify the PI at each participating institution that ethical approval has been withdrawn and for the PI to notify their institution of this. The institution must then suspend or cease participation in the research project.

The monitoring of multi-centre research projects is the subject of a separate guidance document.

Further details about individual components of a best practice research governance framework, linked to the lifecycle of a multi-centre human research project, are discussed below.

The Code and the National Statement address the importance of good institutional governance and management practices in relation to the delivery of quality outcomes for both multi-centre and single centre human research. These national guidance documents form the foundation for good research governance practice. The Code can be found at: http://www.nhmrc.gov.au/guidelines/publications/r39 and the National Statement at: http://www.nhmrc.gov.au/guidelines/publications/e72.

III. National guidance documents

THE CODE – CHAPTER 1:
GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

Sections 1.1 – 1.5 provide guidelines for the responsibilities of institutions relating to the maintenance of an environment that fosters responsible research. Specific guidelines for consideration are at Appendix B.

Sections 1.6-1.11 outline the responsibilities of researchers to foster and maintain a research environment of intellectual honesty and integrity, and scholarly and scientific rigour and well as respecting research participants.

Sections 1.12 and 1.13 set out special responsibilities. It is acknowledged that research with Aboriginal and Torres Strait Islander peoples spans many methodologies and disciplines.

The Code should be read in conjunction with *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (NHMRC 2003) and the *Guidelines for Ethical Research in Indigenous Studies* (Australian and Torres Strait Islander Studies 2002).

Appropriate consumer involvement in research should be encouraged and facilitated by research institutions and researchers. The Code should be read in conjunction with the *Statement on Consumer and Community Participation in Health and Medical Research* (NHMRC and Consumers' Health Forum of Australia Inc, 2002).

THE CODE – CHAPTER 8:
COLLABORATIVE RESEARCH ACROSS INSTITUTIONS

Sections 8.1-8.5 set out the responsibilities of institutions in relation to managing joint research projects, managing conflicts of interest and managing access to research materials. Specific guidelines for consideration are at Appendix B.

THE NATIONAL STATEMENT – CHAPTER 5.1:
INSTITUTIONAL RESPONSIBILITIES

Sections 5.1.1 – 5.1.5 provide guidance on the use of, and institutional responsibility for, research governance activities. Specific guidelines for consideration include:

Section 5.1.2(b)(i-ii) – each institution needs to be satisfied that those conducting its human research are:
- either adequately experienced and qualified, or supervised and
- understand the need to assess risks to their own safety and that of participants.

Section 5.1.5 – institutions should use and promote clearly formulated, documented, accessible and current policies and procedures for research governance and ethical review.

THE NATIONAL STATEMENT – CHAPTER 5.5:
MONITORING OF APPROVED RESEARCH

Sections 5.5.1-5.5.10 provides guidance on monitoring of approved research. Specific advice on monitoring of multi-centre research projects is currently being developed and will form part of this handbook once it is completed.

THE NATIONAL STATEMENT – CHAPTER 5.7:
ACCOUNTABILITY

Chapter 5.7 sets out the different responsibilities the range of stakeholders involved in the ethical design, review and conduct of human research. Specific guidelines for institutions are set out at 5.7.3:
- to ensure that ethical review of research occurs. These responsibilities are set out in Chapter 5.1 Institutional responsibilities: and
- for the conduct of research. These are set out in the Code. They include ensuring that research is both sound and lawful, and is conducted or supervised by educated and experienced researchers.

IV. Linking the components of an institution's research governance framework to the lifecycle of a multi-centre human research project

The components of an institutional research governance framework can be mapped through four project lifecycle stages:
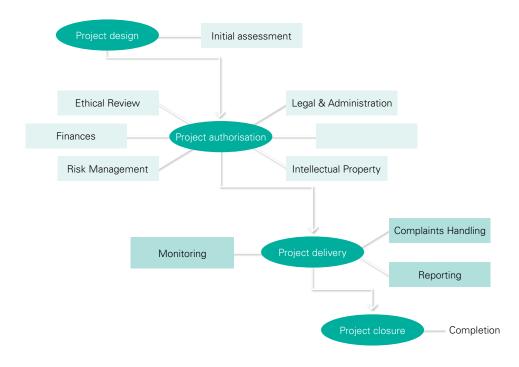
- Stage 1: Project design (concept)

- Stage 2: Project authorisation (pre-commencement)

- Stage 3: Project delivery (post-authorisation to closure)

- Stage 4: Project closure (completion)

The following listing of components of an institutional research governance framework and the activities supporting those components is not exhaustive and should be read in conjunction with any institutional and/or jurisdictional research governance policies that may list additional activities: for example, the Victorian Managed Insurance Authority's *Research Governance Toolkit*.

The listing of the components below is not sequential <u>within</u> each project lifecycle stage, i.e. most of the activities listed occur in parallel rather than in any prescribed order.

Figure 1 is a graphic representation of the elements of research governance.

Flowchart of research governance elements

STAGE 1: PROJECT DESIGN (CONCEPT)

COMPONENT	INITIAL ASSESSMENT OF PROPOSED RESEARCH
Responsible	• Institutional administrators • Principal Investigator
Activities	• Confirmation of the feasibility and alignment of the project design to institutional and/or departmental strategic plans for research. • Peer review of scientific, ethical and practical aspects of proposed project. • Confirmation that the institution has appropriate facilities and other infrastructure. • Confirmation that the institution is appropriately staffed to conduct the particular research and to conduct or support any necessary initial and ongoing training. • Identification of any conflicts of interest. • Preparation and review of risk management strategies. • Identification of funding sources. • Consideration of the suitability of the site for the project (i.e. access to adequate pool of participants). • Establishment of communication between the Principal Investigator and Research Governance Office to help streamline processes and reduce duplication.

STAGE 2: PROJECT AUTHORISATION (PRE-COMMENCEMENT)

COMPONENT	FINANCIAL ASSESSMENT OF PROPOSED RESEARCH
Responsible	• Institutional administrators • Principal Investigator
Activities	• Review of the budget in preparation for final sign off by an appropriate finance authority (e.g. Director of Finance, Head of Department/Division and/or delegate). • Completion of research grant processes (where applicable). • Determination of fees or cost recovery mechanisms (if applicable) for internal and external service providers.

COMPONENT	RISK MANAGEMENT OF PROPOSED RESEARCH
Responsible	• Institutional administrators • Coordinating Principal Investigator • Principal Investigator
Activities	• Identification of potential risks of the proposed research activities to the institution. • Selection of the appropriate risk management strategy to manage risks, including consideration of risk transfer or sharing (e.g. appropriate insurance coverage). • Provision of relevant indemnities, where required, based on the institutional risk profile and chosen management strategy for the given research project.

COMPONENT	ASSESSMENT OF LEGAL AND ADMINISTRATIVE REQUIREMENTS OF PROPOSED RESEARCH
Responsible	• Institutional administrators • Relevant experts
Activities	• Confirmation of roles, responsibilities and accountabilities for all parties involved in the research project (including investigators, sponsors and participants). • Affirmation of institutional compliance with relevant guidelines, regulations, legislation and codes of practice (state and federal) including meeting obligations to the public or non-public collaborators, if any. • Completion of an accepted standard clinical research agreement (where appropriate). • Compliance with notification requirements under the *Therapeutic Goods Act 1989.* • Compliance with requirement to register (where appropriate) clinical trials on a publicly accessible clinical trials registry that complies with the International Committee of Medical Journal Editors (ICMJE). • Review (and completion) of contractual and other legal documentation and confirmation that documentation appropriately reflects the roles, responsibilities and obligations of each party. • Establishment of agreements between collaborating institutions as described in the Code (e.g. conflicts of interest, defining shared roles and responsibilities).

COMPONENT	CREDENTIALING AND SUPERVISION OF PROPOSED RESEARCHERS
Responsible	• Institutional administrators • Principal Investigator
Activities	• Confirmation that investigators and support staff have the appropriate qualifications, authorisation to practice and experience. • Confirmation of arrangements for the supervision and mentoring of student/junior investigators.

COMPONENT	INTELLECTUAL PROPERTY (IP) ARRANGEMENTS COVERING PROPOSED RESEARCH
Responsible	• Institutional administrators • Relevant experts
Activities	• Assurance of protection for the institution's intellectual property. • Negotiation and settlement of issues about authorship, publication and potential commercialisation of research. • Compliance with institutional policy on intellectual property.

COMPONENT	ETHICAL REVIEW OF APPLICATION FOR PROPOSED RESEARCH AND TRANSMISSION OF OUTCOME OF REVIEW
Responsible	• Human Research Ethics Committee (HREC) • Coordinating Principal Investigator with support of Principal Investigators
Activities	• Review and provision of an opinion on the extent to which the research proposal is ethically acceptable and compliant with ethical standards and guidelines (termed 'ethical approval' in the National Statement). • Determination of the need for HREC review or an appropriate authorised alternate review process (e.g. for low risk research). • Notification to relevant bodies (e.g. Therapeutic Goods Administration and the institutions participating in the research) of the outcome of ethical review.

COMPONENT	PROJECT AUTHORISATION
Responsible	• Institutional administrators
Activities	• Assessment that each research governance activity, including site specific assessment and ethical approval, has been satisfactorily completed. • Authorised research to commence in institution and notification provided to the Coordinating Principal Investigator.

STAGE 3: PROJECT DELIVERY (POST-AUTHORISATION TO CLOSURE)

COMPONENT	MONITORING OF PROPOSED RESEARCH
Responsible	• Institutional administrators • Human Research Ethics Committee (HREC) • Principal Investigator (reporting to HREC via Coordinating Principal Investigator)
Activities	• Monitoring and review of safety of all research participants and compliance with adverse event reporting requirements. • Management of data management and storage. • Management of privacy requirements and confidentiality of research data. • Delivery of quality control processes (including supervision of staff and record-keeping). • Training and/or mentoring of investigators regarding monitoring requirements. • Monitoring of expenditure and budget. • Clarification and assignment of responsibility within institution for monitoring conduct of research. Typically, this responsibility is delegated to the Research Governance Office or an equivalent individual or group. • Demonstration that relevant institutional staff understand and follow the process for information sharing between the institution, collaborating institutions and the HREC that conducted the review. The Coordinating Principal Investigator has the lead role for communication between the Principal Investigators at each institution and the HREC. • Compliance with the requirements of and timeframes for reporting on project progress. • Measurement of performance against agreed targets (where appropriate) and modification of processes as needed.

COMPONENT	COMPLAINTS MANAGEMENT AND MANAGEMENT OF ALLEGATIONS CONCERNING RESEARCH MISCONDUCT
Responsible	• Institutional administrators • Principal Investigator • Human Research Ethics Committee (HREC)
Activities	• Compliance with institutional process for managing allegations of research misconduct and complaints. • Incorporation of the principles of natural justice and independence into management of complaints and allegations. • Assurance that the complaints process is transparent and communicated to relevant stakeholders and is undertaken in accordance with the requirements set out in the Code.

COMPONENT	REPORTING
Responsible	• Principal Investigator • Coordinating Principal Investigator (to HREC) • Institutional administrators
Activities	• Conduct of self-audit on compliance with good research practice guidelines. • Safety reporting. • Compliance with internal and external reporting obligations, including safety reporting and reporting to the HREC. • Provision of training on reporting for investigators and administrators to encourage culture of oversight and review.

STAGE 4: PROJECT CLOSURE (COMPLETION)

COMPONENT	COMPLETION
Responsible	• Principal Investigator • Institutional administrators
Activities	• Confirmation that project closure is orderly and systematic. • Completion of an end-of-project checklist. • Provision of research outcomes to participants (where required). • Compliance with record storage policies (including future destruction). • Follow up on intellectual property and commercialisation activities (where applicable). • Reporting of outcomes to participants, funding bodies and other stakeholders (where applicable).

V. Roles and responsibilities of key stakeholders within the institution's research governance framework for multi-centre human research

In the context of the HoMER initiative, good practice in research governance of multi-centre human research demonstrates a clear distinction between institutional research governance responsibilities and the ethical review responsibilities of an Human Research Ethics Committee (HREC). Everyone involved in human research has a personal responsibility to understand and comply with the relevant administrative or statutory arrangements of the institution, the relevant jurisdiction and national guidance documents.

The table below expands on the roles and responsibilities of institutional stakeholders in the governance of multi-centre human research.

KEY STAKEHOLDER	ROLE	RESPONSIBILITY
Coordinating Principal Investigator (CPI)	The person who has overall responsibility for coordinating the administrative processes of the ethical review of a multi-centre human research project. This includes, but is not limited to: • communicating the outcome of the single ethical review to Principal Investigators at each institution • coordinating the on-going reporting of the ethical progress of the research project to the HREC and/or sponsors (where required). This person may or may not be employed by an institution participating in the research project. *Note: It is considered best practice for all multi-centre research projects undergoing single ethical review to have a designated CPI, regardless of which sector the research is occurring in or the type of research project being conducted.*	• Compile a National Ethics Application Form (NEAF) with input from participating institutions. • Submit the NEAF, with supporting documentation, to an HREC that uses certified ethical review processes. • Relay information as necessary and in a timely manner between Principal Investigators and the HREC (e.g. queries, notification of project authorisation and research commencement, required reporting). • Submit reports related to the ethical conduct of an approved multi-centre human research project as required by the HREC. • Co-ordinate the provision of necessary documentation in the event of an investigation of research misconduct.

KEY STAKEHOLDER	ROLE	RESPONSIBILITY
Principal Investigator(s) (PI)	The person(s) responsible, either as an individual or as the leader of investigators within an institution, for the conduct of a research project at that institution.	• Provide Coordinating Principal Investigator (CPI) with information to complete the NEAF.
		• Provide relevant information to the research governance office (or equivalent body or individual) in a timely manner (i.e. in parallel to ethical review process) to enable the institution to begin the site assessment process where appropriate.
		• Provide ethical review information to the research governance office (or equivalent body or individual) as the initial review outcome or subsequent changes become available.
		• Provide the approving HREC (via the CPI if required) with a regular report on routine monitoring including concerns or issues arising from local audit.
		• To comply with Good Clinical Practice guidelines as appropriate.
		• Conduct multi-centre human research projects in accordance with the agreed protocol, relevant administrative or statutory requirements and national and international guidance.
		• Prepare and provide information for participants of multi-centre human research projects at a local level that relates specifically to the institution.
		• Ensure participants' safety and welfare during the research project.
		• Arrange to make findings and/or data accessible following peer review.
		• Notify CPI of research commencement, where appropriate.
		• Comply with institutional reporting requirements related to the multi-centre human research project, where appropriate. Provide CPI with information to enable reporting to the HREC.
		• Comply with institutional financial management and other requirements regarding research projects.

V. Roles and responsibilities of key stakeholders within the institution's research governance framework for multi-centre human research

KEY STAKEHOLDER	ROLE	RESPONSIBILITY
Investigator(s) (e.g. Associate or Assistant)	The person(s) involved in and/or conducting the research project. May also broadly refer to individuals supporting the conduct of research.	• Be involved and/or conduct multi-centre human research projects in accordance with the agreed protocol, relevant administrative or statutory requirements and national guidance. • Ensure participants' safety and welfare during the research project. • Comply with institutional financial management, institutional policies on governance (such as Good Clinical Practice guidelines) and other requirements regarding research projects.
Institution	In this document, the term institution is used broadly to mean a research institution, organisation or, in certain cases, individuals or jurisdictions (States and Territories of Australia), either in the public or private sector, under whose authority research is conducted.	• Oversee the conduct of research including establishment of structures and processes to monitor research. • Determine the level of resourcing for the support of research activities within the institution (e.g. people and money). • Comply with relevant statutory and administrative requirements including the establishment of processes that support or monitor those requirements. • Train investigators and research governance officers to fulfil their obligations within human research. • Investigate complaints and allegations of research misconduct. • Utilise the outcome of a single ethical review of multi-centre human research conducted by an HREC using certified ethical review processes. • Authorise, or not, the commencement of research approved by an HREC. • Foster and support the development of intellectual property. • Provide indemnity and insurance coverage for research (where applicable).

KEY STAKEHOLDER	ROLE	RESPONSIBILITY
Institutional Research Governance Office	The designated administrative area within an institution that is resourced to enable research proposals to be appropriately assessed so to assist the decision-maker to determine whether or not the research project will be authorised.	• Establish efficient processes for site assessment and overall research governance activities to be conducted. • Advise the authorising officer about the strategic fit of a proposed research project for their institution. • Determine and approve the financial management conditions and/or the funding source for the proposed research for the duration of the project. • Assess the institution's risk exposure through risk assessment processes including choosing appropriate strategies for managing risk (e.g. appropriate insurance cover and/or indemnity agreements). • Review and negotiate contracts, in consultation with relevant specialists as required, including, but not limited to, clinical research agreements, confidentiality agreements and those relating to conditions of employment for investigators. • Review intellectual property issues, in consultation with relevant specialists as required. • Ensure compliance with relevant guidelines, regulations, and legislation (institutional, State and Federal). • Process complaints relating to the conduct of research at the institution in accordance with institutional complaints policy and processes. • Monitor conduct of research within the institution.
Institutional authorising officer	The officer (or their delegate) within an institution who has the authority to authorise the commencement of a research project at their site. It is best practice for this authorisation to be function of a delegate who is not a member of the ethical review body that approved the research.	• Provide authorisation for the approval of the commencement of an ethically approved research project at their institution.

V. Roles and responsibilities of key stakeholders within the institution's research governance framework for multi-centre human research

KEY STAKEHOLDER	ROLE	RESPONSIBILITY
Human Research Ethics Committee (HREC) reviewing multi-centre human research	The body established in accordance with Chapter 5.1 of the National Statement that conducts the ethical review of a multi-centre human research project using certified ethical review processes. The HREC may or may not belong to one of the institutions participating in the multi-centre research project.	• Review a multi-centre human research proposal to form a view on its ethical acceptability (in accordance with the National Statement). • Ensure project is compliant with relevant guidelines, regulations and legislation (institutional, State and Federal). • Provide the Coordinating Principal Investigator, and/or the Principal Investigator, with the outcome of the ethical review of the multi-centre human research project. • Advise and receive reports from institutions regarding complaints or reports of research misconduct arising out of the conduct of approved multi-centre human research. • Monitor research for which it has given approval, through the receipt of safety, progress and any other required reports in conjunction with the participating institutions and their research governance offices.

Appendix A

RESEARCH GOVERNANCE PRACTICES FOR PUBLIC HEALTH ORGANISATIONS

The following links to the websites of State and Territory Health Departments provide information about research governance practices for public health organisations:

Australian Capital Territory
http://www.health.act.gov.au/c/health?a=da&did=10051705&pid=1054022557

New South Wales
http://www.health.nsw.gov.au/ethics/research/index.asp

Northern Territory
http://www.health.nt.gov.au/For_Professionals/Research/index.aspx (under review)

Queensland
http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

South Australia
http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/research

Tasmania
http://www.research.utas.edu.au/human_ethics/index.htm

Victoria
http://www.health.vic.gov.au/cchre/applications_site_specific.htm

Western Australia
http://www.shrac.health.wa.gov.au/home/

Appendix B

EXTRACTS FROM NATIONAL GUIDANCE DOCUMENTS

THE CODE – CHAPTER 1: GENERAL PRINCIPLES OF RESPONSIBLE RESEARCH

Section 1.2 – Establish good governance and management practices

- 1.2.1 – each institution should provide an appropriate research governance framework through which research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability. The framework should specify the roles, responsibilities and accountabilities of all those who play a part in research.

- 1.2.2 – the research governance framework should demand compliance with laws, regulations, guidelines and codes of practice governing the conduct of research in Australia. Common law obligations also arise from the relationships between institutions, investigators and participants, while contractual arrangements may impose further obligations.

- 1.2.3 – each institution must ensure the availability of the documents that help guide good research governance, conduct and management.

- 1.2.4 – there must be a clear policy on collaborative research projects with other organisations, which requires arrangements to be agreed before a project begins. As a minimum, these arrangements should cover financial management, intellectual property, authorship and publication, consultancies, secondments, ethics approval, and ownership of equipment and data.

- 1.2.5 – each institution must have a well-defined process for receiving and managing allegations of research misconduct.

- 1.2.6 – there must be a process for regular monitoring of the institution's performance with regard to these guidelines.

Section 1.3 – Train staff

- It is important that institutions provide induction, formal training and continuing education for all research staff, including research trainees. Training should cover research methods, ethics, confidentiality, data storage and records retention, as well as regulation and governance. Training should also cover the institution's policies regarding responsible research conduct, all aspects of this Code, and other sources of guidance that are available. Institutions may make arrangements for joint induction and training with other institutions.

THE CODE – CHAPTER 8:
COLLABORATIVE RESEARCH ACROSS INSTITUTIONS

- 8.1 Establish agreements for each collaboration

  o   Organisations involved in a joint research project should ensure that an agreement is reached with the partners on the management of the research. Such an agreement should follow the general principles of this Code, including integrity, honesty and a commitment to excellence.

  o   The agreement should be in writing. It must cover intellectual property, confidentiality and copyright issues; sharing commercial returns, responsibility for ethics and safety clearances; and reporting to appropriate agencies. It should address the protocols to be followed by the partners when disseminating the research outcomes, and the management of primary research materials and research data.

  o   The agreement may take various forms, including a legal contract signed by the chief executive officer, an exchange of letters, or a research management plan signed by all parties, or management plans signed by appropriate representatives from all parties.

  o   Each organisation must ensure that its investigators are aware of, and understand, the policy and agreements governing the joint research collaboration.

  - 8.2 Manage conflicts of interest

    Institutions must have a policy for managing conflicts of interest that arise in collaborative research (see Section 7).

  - 8.3 Manage access to research materials

    The collaborating parties should each identify a person to be involved in the management of research data, primary materials and other items to be retained at the end of the project.

Responsibilities of investigators

- 8.4 Comply with multi-institutional agreements

  Investigators involved in joint research must be aware of, and comply with, all policies and written agreements affecting the project, particularly those relating to the dissemination of research findings and the management of research data and primary materials.

- 8.5 Declare conflicts of interest

  When establishing a research collaboration, investigators must disclose as soon as possible any actual or apparent conflicts of interest relating to any aspect of the project.