Consultation Document

Harmonisation of Multi-centre Ethical Review (HoMER) enabling system

Proposed national approach for the adoption of a single ethical and scientific review for multi-centre health and medical human research

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Abbreviations used in this document

AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers Advisory Council
ARC	Australian Research Council
ASC	Aboriginal Sub-Committee
ATSIRAC	Aboriginal and Torres Strait Islander Health Advisory Committee
AVCC	Australian Vice Chancellors' Committee
CHREC	Central Human Research Ethics Committee(s) (Victoria)
CTA	Clinical Trials Australia
CTN	Clinical Trial Notification (TGA)
CTX	Clinical Trial Exemption (TGA)
DHHS	Department of Health and Human Services (Tasmania)
DM	District Manager (Queensland)
HoMER	Harmonisation of Multi-centre Ethical Review
HREC	Human Research Ethics Committee(s)
IT	Information Technology
KPI	Key Performance Indicator
LC	Lead Committee (NSW)
MAM4MCR	Mutual Acceptance Model for Multi-Centre Research (Qld)
MOU	Memorandum of Understanding
NEAF 2.0	National Ethics Application Form (version 2.0)
NHMRC	National Health and Medical Research Council
PI	Principal Investigator
QH	Queensland Health
RGO	Research Governance Officer
SAE	Serious Adverse Event
SOP	Standard Operating Procedure(s)
SSA	Site-Specific Assessment
SUSAR	Suspected Unexpected Serious Adverse Reactions
TGA	Therapeutic Goods Administration
UTAS	University of Tasmania

Executive summary

The objective of the Harmonisation of Multi-centre Ethical Review (HoMER) enabling system is to establish a system enabling the recognition of a single ethical and scientific review of multi-centre health and medical human research within and/or across Australian jurisdictions.

An introduction to the purpose and anticipated benefit of the HoMER enabling system and descriptors of existing jurisdictional systems and structures is at Part A (with further detail at Appendix A).

The key elements of the proposed national approach are:

- enabling existing and planned jurisdictional level systems of streamlined ethical and scientific review processes to work together
- standardised policies, processes and procedures in relation to single ethical and scientific review
- acceptance of a single ethical and scientific review by institutions participating in multi-centre health and medical human research
- institutional HRECs being assessed and accredited to conduct the single ethical and scientific review of a multi-centre research proposal
- conformance to national guidance on the ethical conduct of human research and the responsible conduct of research and relevant statutory and administrative frameworks.

Consultation on this document is a major milestone in the establishment of the HoMER enabling system. The anticipated timelines for the phased implementation of the proposed national approach is at Figure 2.

Part B and Part C outline proposed structures, roles and responsibilities of key stakeholders and address the essential features of the HoMER enabling system. NHMRC will conduct future targeted consultation to assist with the finalisation of how aspects of the proposed national approach will operate.

Part D discusses the maintenance and improvement of the proposed HoMER enabling system following its full implementation.

Part A Introduction

1 Background

1.1 The National Health and Medical Research Council (NHMRC) is Australia's leading funding body for health and medical research. NHMRC also provides the government, health professionals and the community with expert and independent advice on a range of issues that directly affect the health and well being of all Australians.

1.2 NHMRC is internationally recognised as an expert body in:

- supporting health and medical research
- developing health advice for the Australian community, health professionals and government
- providing advice on ethical behaviour in health care and in the conduct of health and medical research.

The Harmonisation of Multi-centre Ethical Review (HoMER) enabling system

1.3 In 2006, an inter-jurisdictional working party was established to advise the Australian Health Ministers Advisory Council (AHMAC) on the issues and options for simplifying multi-centre health and medical research ethical review in Australia. AHMAC recognised that ethical and scientific reviews spanning more than one jurisdiction faced particular problems.

1.4 AHMAC commissioned NHMRC to take on the role as coordinator to implement a nationally harmonised system where a single ethical and scientific review carried out by a recognised Human Research Ethics Committee (HREC) would be accepted by institutions across and/or within jurisdictions. NHMRC was asked to provide a detailed budget for the proposed national approach. The detail of the budget, including the identification of and sourcing for resources needed for the ongoing delivery of the proposed national approach, will be developed in cooperation with jurisdictions following AHMAC agreement to a final system model (i.e. mid 2009).

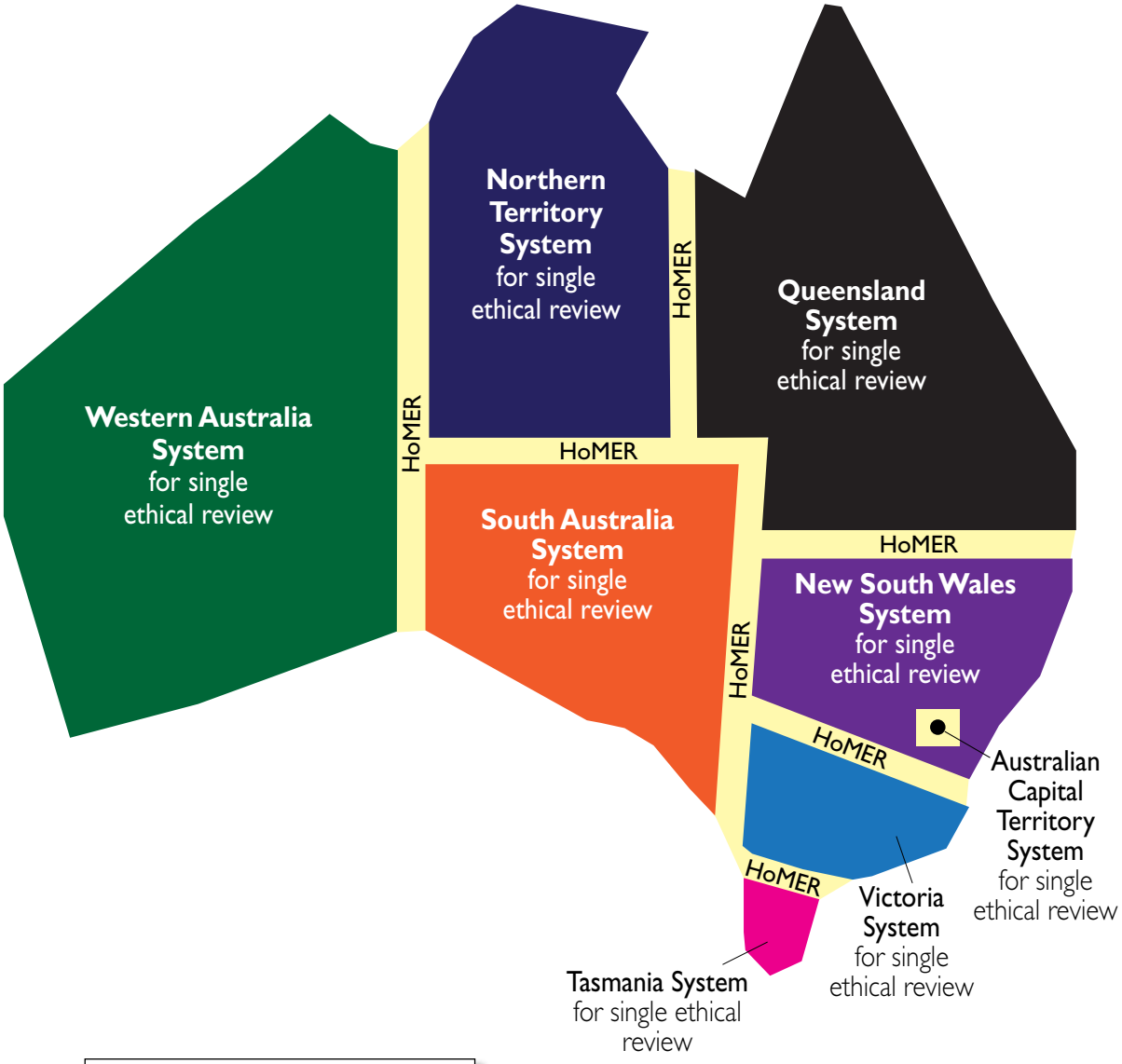
1.5 There are currently over 250 HRECs across Australia. For researchers planning multi-centre health and medical research projects across and/or within Australian jurisdictions, the practice of applying to a number of HRECs can result in considerable delays and additional costs to the proposed research program.

1.6 The implementation of the proposed HoMER enabling system, as discussed in this document, will ideally streamline the ethical review of multi-centre health and medical research proposals.

1.7 The proposed HoMER enabling system will integrate standards, standardised forms, processes and procedures, with existing and similar systems operating in States and Territories (*Part A4 Existing jurisdictional approaches*). Institutions, researchers and other research stakeholders will engage with the proposed national approach through the existing system in their jurisdiction.

1.8 Figure 1 sets out the relationship of the proposed HoMER enabling system and the existing systems operating in Australian States and Territories:

Figure 1: Proposed HoMER enabling system and the existing systems operating in Australian States and Territories



The pathway represents the proposed HoMER enabling system of consistent policies, processes and procedures adopted and implemented in jurisdictional systems

Progress in implementing a national approach

1.9 NHMRC has established several key advisory bodies to assist in the development of the proposed HoMER enabling system.

1.10 The advisory bodies include:

- *HoMER Reference Group* – membership drawn from State and Territory government agencies, the Australian Health Ethics Committee, the Group of 8 universities, the pharmaceutical industry, the Therapeutic Goods Administration, the Department of Health and Ageing and individuals with expertise in conducting multi-centre health and medical research and ethical and scientific reviews of research proposals.
- *HoMER Jurisdictional Group* – membership drawn from state and territory health departments.
- *HoMER subgroups with specific expertise* – membership drawn from key stakeholders in the proposed HoMER enabling system. The subgroups will consider the following system features:
  - accreditation of HRECs
  - indemnity and insurance matters
  - monitoring and compliance matters
  - standardisation of forms
  - information capture and transfer (including IT tools)
  - training requirements
  - data management
  - costing and fees.

1.11 NHMRC held a series of jurisdictional focus groups in July and August 2008 to identify the critical features for the proposed HoMER enabling system. This consultation document has been created to seek wider input into the question of what should be the structure and features of the proposed HoMER enabling system.

1.12 At the same time, it is recognised that the detail of how the proposed HoMER enabling system should operate within a jurisdictional system will, in some cases, need further development. Following the consideration of submissions on this document, further focus groups and stakeholder engagement activities are planned.

1.13 An indicative timeline for the development of the detail of the proposed HoMER enabling system's operation is presented at *Part A2 Introduction to the proposed national approach*.

Part A

2 Introduction to the proposed national approach

2.1 The objective for the Harmonisation of Multi-centre Ethical Review (HoMER) enabling system is:

> *to establish a system enabling the recognition of a single ethical and scientific review of multi-centre health and medical human research within and/or across Australian jurisdictions.*

2.2 The single ethical and scientific review within the proposed national approach will promote ethically good human research and allow research participants to be accorded the respect and protection that is due to them. Furthermore, the implementation of the proposed national approach assists each institution to meet its responsibility to adopt a review process that eliminates any unnecessary duplication of ethical and scientific review.

2.3 The perceived benefits of the proposed HoMER enabling system are:

- reduced timelines for ethical and scientific review of human research
- reduced duplication of ethical and scientific review of multi-centre health and medical research
- coordinated approval of multi-centre health and medical research
- adoption of standardised ethical and scientific review processes and procedures
- stakeholder confidence that all relevant ethical aspects have been identified and reviewed
- clearer understanding of research governance and institutional responsibility in ethical and scientific review
- enhanced Australian leadership in ethical and scientific review practice
- efficient use of resources for research administration.

2.4 The proposed HoMER enabling system is complex as its implementation involves the interests and practice of a diverse range of stakeholders including researchers, institutions, government agencies and commercial sponsors. The proposed HoMER enabling system will impact existing administrative processes and procedures for ethical and scientific review of multi-centre health and medical research in Australia.

2.5 The proposed HoMER enabling system will not replace, nor be imposed on top of, existing or developing jurisdictional arrangements. Rather, it will lead to increased efficiency and effectiveness of ethical and scientific review processes of multi-centre research by enabling the national adoption and implementation of consistent policy, processes and procedures.

2.6 In addition to the improved efficiency and effectiveness of ethical and scientific review processes, the proposed HoMER enabling system will support researchers, institutional administrators and HRECs whose institutions participate in multi-centre research to rationalise their workloads.

2.7 The purpose of this consultation document is to consult stakeholders on the key elements of the proposed HoMER enabling system so that the underlying details can then be developed in consultation with all stakeholders.

2.8 The Australian Government has funded the development and initial implementation of system features for the proposed HoMER enabling system for the period 2007-2011.

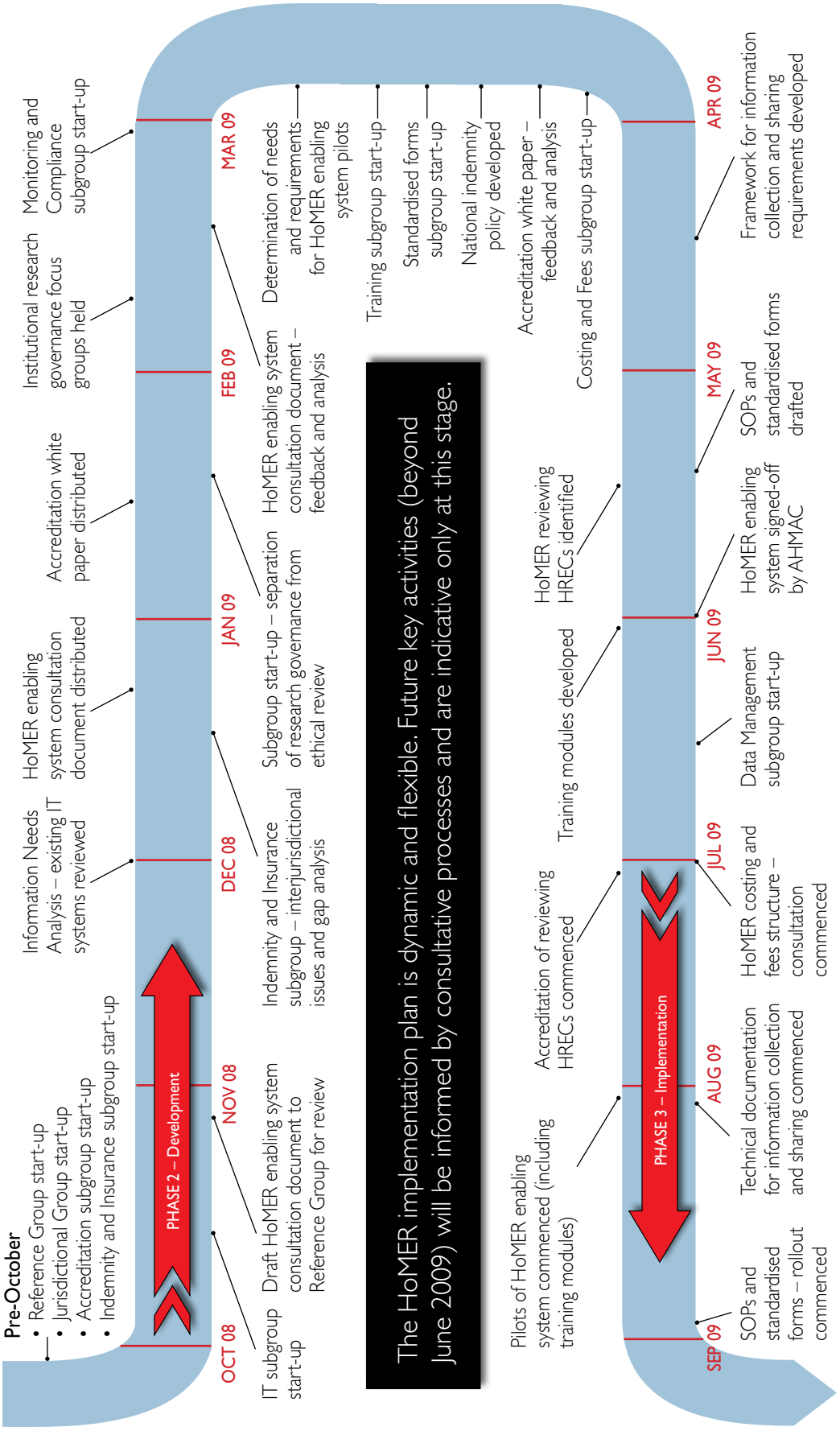
Figure 2 shows the indicative timeline for developing and implementing the HoMER enabling system.

Questions:

2A Is the suggested timeline for developing and implementing the HoMER enabling system reasonable? If not, why not?

2B Are there specified milestone dates that require adjustment? If so, please provide the reasoning for their adjustment.

Figure 2: Indicative timeline for implementation of the national approach



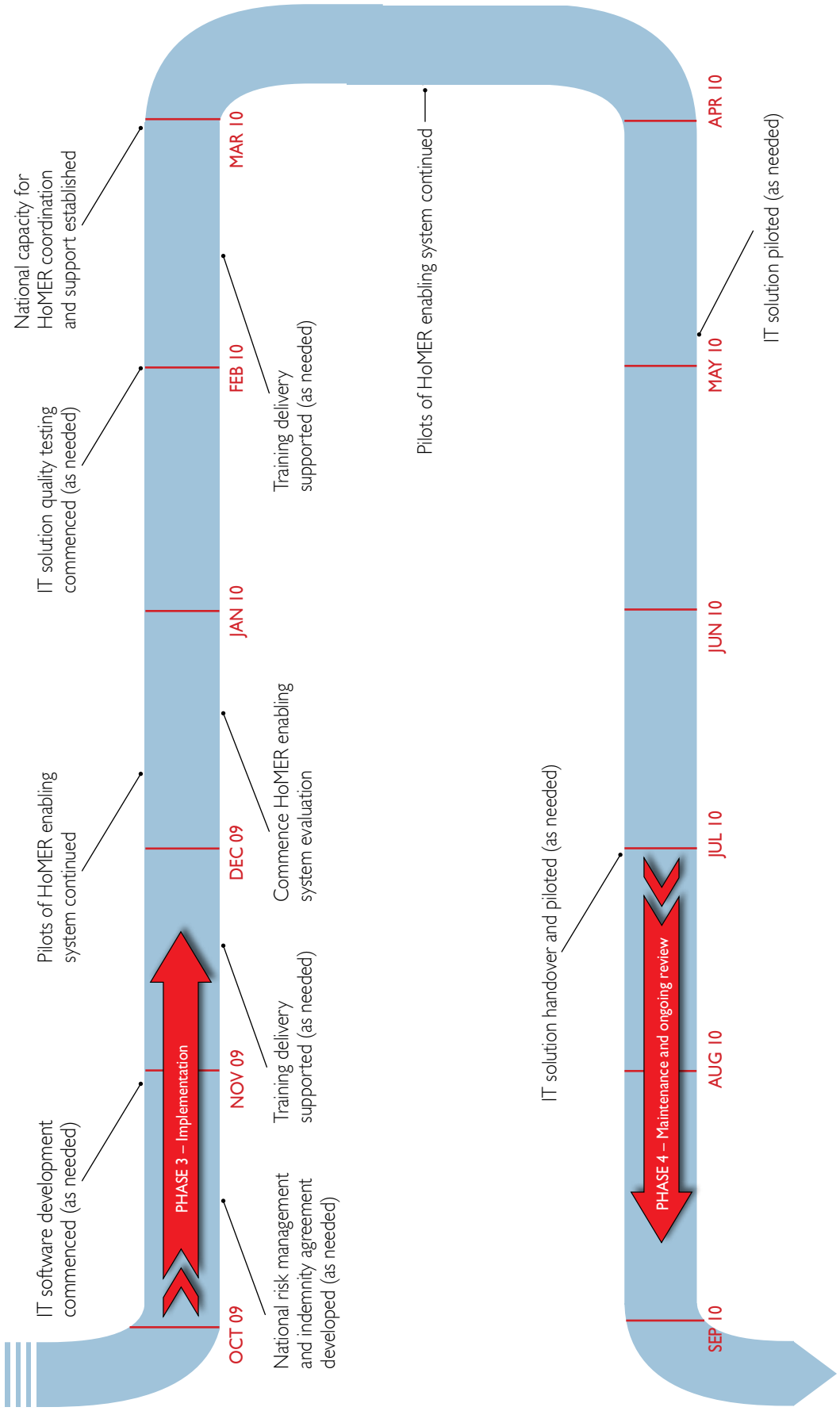


Figure 2 (continued): Indicative timeline for implementation of the national approach

Part A

3 Regulatory and administrative frameworks

3.1 Ethical and scientific reviews are not prescribed in law, although applicable Australian, State and Territory legislation needs to be considered during the review process. Relevant areas of law include privacy, guardianship, and research involving unapproved therapeutics or the use of human tissues. In addition, jurisdictions may have mandatory administrative requirements that guide ethical and scientific review processes.

3.2 Within the proposed HoMER enabling system, the reviewing HREC must be familiar with the jurisdictions' legislation and administrative requirements that apply to the proposed research where the research will be carried out. All institutions and project researchers participating in the research will need to be familiar with the relevant law and administrative requirements operating in their own jurisdiction.

3.3 To provide operational guidance to institutions and researchers, NHMRC has published two documents in relation to the conduct of responsible research and ethical and scientific review of human research:

- NHMRC/ARC/Universities Australia *Australian Code for the Responsible Conduct of Research* (2007) (the Code)
- NHMRC/ARC/AVCC *National Statement on Ethical Conduct of Human Research* (2007) (the National Statement).

Compliance with both these documents is a condition of contracts entered into between Australian Government funding bodies and researchers.

Privacy legislation

3.4 If human research involves personal information about an individual, there are Australian, State and Territory laws that control the collection, storage, use and disclosure of that information. Privacy laws also describe when the individual's permission (or consent) must be obtained for the collection, use and disclosure of information about themselves and when consent may be waived.

Guardianship legislation

3.5 Some jurisdictions have legislation regarding consent processes for individuals who lack the capacity to decide whether or not to participate in medical research. As with privacy laws, the reviewing HREC, researchers and participating institutions will need to be familiar with and comply with the relevant law.

Unapproved therapeutic goods

3.6 The Therapeutic Goods Administration (TGA) requires clinical trials of unapproved therapeutics to be reviewed by a HREC.

3.7 Two schemes specifying the processes for the conduct of clinical trials involving unapproved therapeutic goods have been established under the Therapeutic Administration Act. These schemes are the Clinical Trial Exemption (CTX) Scheme and the Clinical Trial Notification (CTN) Scheme. Research proposals for either scheme could be reviewed under the proposed national approach.

3.8 The TGA has published guidance on the role of Human Research Ethics Committees in reviewing clinical trials:

- *Human Research Ethics Committees and the Therapeutic Goods Legislation* (2001).

Use of human tissue legislation

3.9 While the National Statement provides guidance on research using human tissue samples, jurisdictional legislation will need to be taken into account by the reviewing HREC of multi-centre health and medical research proposals.

Questions:

3A Is it reasonable that the single-reviewing HREC is familiar with the statutory and administrative frameworks operating in the jurisdictions where the proposed research will be conducted?

3B Would providing the single-reviewing HREC with summary information on all jurisdictional statutory and administrative frameworks (e.g. a booklet outlining relevant information) be sufficient to support their ability to review cross jurisdictional research proposals? If not, how could the appropriate level of familiarity be assured?

Part A

4 Existing jurisdictional approaches

4.1 Australian States and Territories have or are progressing systems to streamline ethical and scientific review processes for multi-centre health and medical research carried out within their borders. These systems will adopt and implement the proposed HoMER policies, processes and procedures outlined in this document subject to AHMAC agreement.

4.2 Further detail and diagrams showing the varying approaches can be found at *Appendix A: Existing jurisdictional systems*.

Australian Capital Territory (ACT)

4.3 ACT Health is currently examining, with the assistance of the ACT Health and Medical Research Council (a ministerially appointed advisory council), various models to provide an overarching governance structure for research across the portfolio. ACT Health is also preparing a government response to a recent inquiry of the Legislative Assembly Standing Committee on Health and Disability on Health Science in the ACT. The issue of ensuring timely and efficient ethical review of research, not only within the portfolio but across the ACT, is being considered within this context.

New South Wales (NSW)

4.4 In 2007, a system of single ethical and scientific review of multi-centre health and medical research was implemented with the aim that every research project conducted within the NSW public health system is scientifically and ethically reviewed once only.

In NSW Human Research Ethics Committees (HRECs) fall into two categories: Lead HRECs and Local HRECs. Lead HRECs are accredited to conduct single ethical review of multi-centre health and medical research on behalf of all public health sites in NSW at which a research project is to be conducted.

Approval for research projects comprises ethics review and research governance processes. The research governance aspect is conducted through a site specific assessment. Through this assessment, a public health organisation considers whether it has the capacity to participate in the research at that site. Research projects must satisfy the requirements of both processes for approval to commence. Special provisions are made for research projects on persons in custody, Aboriginal people and State-wide data collections.

Northern Territory

4.5 There are two Ethics Committees within the Northern Territory. The Human Research Ethics Committee of the Northern Territory Department of Health & Families and the Menzies School of Health Research considers applications for research by government and non-government health providers within the Northern region. This Committee has a separate Aboriginal Sub-Committee (ASC), which exists to advise the main Committee. The ASC is deemed to be of paramount importance to the decision making process of the main Committee due to the large population of Aboriginal people within the NT.

The Central Australian Human Research Ethics Committee considers applications for research on humans for all organisations and individuals who wish to conduct such research in Central Australia.

Queensland

4.6 Queensland Health (QH) evaluated a pilot program of single review of multi-centre health and medical research in 2006 which required the 7 pilot sites in the public sector to mutually accept / recognise the ethical and scientific review outcome of another QH HREC. One of the most significant insights gained from the QH pilot-evaluation has been that even the 'best designed' model for single ethical review of multi-centre health and medical research will not deliver desired efficiencies and standards if it is placed within a larger system that fails to support the very dynamics upon which the model rests.

As a result of this pilot evaluation the model has been re-designed. The key feature of this model is the separation of the ethical and scientific review process from research governance in a linear fashion. The model is to be amenable to future incorporation of some Queensland based, non-QH entities (e.g., the university and private hospital sectors) into the QH mutual acceptance system. QH is now working with its public sector HRECs to progress to a single review model. This will be underpinned by a number of training and education initiatives developed locally, use of standard operating procedures, the use of a Web base research ethics database and information sessions for other key stakeholders.

South Australia (SA)

4.7 The Department of Health commissioned Professor Michael Frommer and his team to undertake a review of research ethics processes in the public health system of South Australia. The aim of this review was to provide detailed recommendations to the Department of Health regarding ways in which the current system can be improved to ensure the timely and efficient ethical review of research, including potential streamlining of processes. The review considered all research types conducted within the public health system, e.g. clinical trials, population health, social health, data linkage and epidemiological studies.

The final report from this review has been provided to the Department of Health. Consideration is currently being given to the recommendations presented by Professor Frommer. A forum of HREC Chairs was held in early December to discuss the recommendations in greater detail and determine an appropriate way forward for SA. South Australia will continue to be actively involved in and guided by the initiatives occurring at a national level.

Tasmania

4.8 Tasmania has adopted a unified Human Research Ethics Committee (Tasmania) Network. The Network is a cooperative arrangement between the Department of Health and Human Services and the University of Tasmania with all human research ethical review being carried out by two NHMRC registered Human Research Ethics Committees. In addition a scientific advisory committee that considers the scientific validity of research methodology before an application is given ethical assessment.

Victoria

4.9 Victoria has developed a system for streamlining ethical review of multi-site research and will implement this in 2009. In the first phase commercially sponsored clinical trials will be reviewed and thereafter other types of human research could be introduced in a stepwise approach. Both public and private health care organisations will have the opportunity to participate in this system.

- The streamlined approach is designed with a governance body (Consultative Council) and a centralised secretariat that will triage ethics applications to reviewing Human Research Ethics Committees (HRECs). HREC meetings will be staggered so that a meeting will be held each week, thus allowing for timely entry of applications into the review system.
- Research governance matters should be separated from ethical and scientific review with both these processes occurring in parallel. Site-specific assessment by institutions participating in a research project will provide information to determine the institution's capacity to participate. Both ethical review approval and authorisation of site-specific assessment will be required before a research project can commence at a site.

Western Australia (WA)

4.10 Western Australia's approach to multi-centre health and medical research is:

- A 'recognised prior review' pathway exists which allows a WA HREC to consider a review undertaken at another HREC if that HREC has conducted a full ethical and scientific review and granted approval.
- This pathway essentially enables an 'accept or reject' decision to be made in conjunction with the site specific governance review
- Specific HRECs review applications in respect to research that involves i) Aboriginal people or ii) use and disclosure of personal health information held in the Department of Health WA data collections.

Part B The proposed HoMER enabling system

5 Scope of the proposed HoMER enabling system

5.1 The proposed HoMER enabling system's objective is to establish a system enabling the recognition of a single ethical and scientific review of multi-centre health and medical human research within and/or across Australian jurisdictions. All ethical and scientific review processes in the proposed national approach will follow the National Statement and the Code.

5.2 Initially only the HRECs of public hospitals, research institutes based in public institutions, government agencies and publicly funded universities will be eligible to be a single-reviewing HREC.

5.3 The proposed HoMER enabling system will initially include a broad range of categories of human research. These include both investigator and commercially sponsored clinical trials, epidemiological research and other health and social research where the focus is on human health and wellbeing.

5.4 As the proposed national approach is implemented through existing and planned jurisdictional systems there may be restrictions on the type of institution, or the category of research, included in the scope of jurisdictional systems. For example, institutions in the private sector may not be included in one or more jurisdictions.

5.5 The consequence of such a restriction is that the pool of HRECs carrying out the single ethical and scientific review will only be drawn from the institutions that are included within the scope of jurisdictional systems.

5.6 Even in the case of a type of institution being excluded from the scope of a jurisdictional system, the institution may still participate in multi-centre health and medical research. In this instance, the institution would retain its autonomy in determining whether to accept the single ethical and scientific review of the reviewing HREC, or alternatively, conduct its own ethical and scientific review of the research proposal.

5.7 It is anticipated that the HoMER enabling system will undergo further phased implementation to allow for greater inclusiveness of institutions whose participation may be initially restricted in part or in whole.

5.8 In addition, certain categories of human research may be excluded from the existing and planned jurisdictional systems and/or legislative frameworks and, therefore, from the initial implementation of the national approach. An example is multi-centre health and medical research involving prisoners as there are different legislative frameworks within jurisdictions.

5.9 Multi-centre animal research is not part of the proposed national approach.

5.10 Research conducted by only a single institution, at single or multiple sites, is not in the scope of the proposed HoMER enabling system.

Questions:

5A Is the proposed scope appropriate?

5B What types of institutions, if any, should be restricted from participating in the proposed national approach?

5C What categories of human research should be excluded, if any?

5D Should there be a consistent set of eligible institutions in all Australian jurisdictions as distinct from an approach that is jurisdictionally-based?

5E Should the scope of the proposed national approach change over time?

5F What would need to be in place to facilitate the scope changing over time?

Part B

6 Structure and processes

6.1 The proposed HoMER enabling system, as a 'harmonised' national approach, must be flexible enough to include the different initiatives of the States and Territories in streamlining ethical and scientific review of multi-centre health and medical research (*Part A4 Existing jurisdictional approaches*), as well as allowing for different institutional arrangements for managing ethical and scientific review and research governance.

6.2 The proposed national approach will be delivered at three levels – National, Jurisdictional and Institutional. The Jurisdictional level is subdivided into jurisdictional activity carried out by a state or territory government health agency and activity carried out by an institution interacting with the relevant health agency.

6.3 National level coordination (shown in green on Figure 3) will develop, support and coordinate policies and processes for the proposed national system. The components of this level of activity include:

- a system of accreditation for HRECs
- national and cross-jurisdictional guidance on indemnity and insurance issues
- policies and procedures that distinguish (and separate) ethical and scientific review from research governance
- a national approach to information collection, management and sharing
- standardisation of forms for research governance, ethical and scientific review processes and reporting
- guidance on costing and fee structures for multi-centre ethical and scientific review
- on-going monitoring of the proposed national approach.

NHMRC and jurisdictions will collaborate in determining the optimal placement of a national coordinating body for the ongoing implementation of the proposed national approach.

6.4 Standardised policy, procedures and processes may be necessary. The national coordinating body will ensure these areas of system support are developed in consultation with key stakeholders, including State and Territory government agencies, institutions, institutional HRECs, researchers and research sponsors.

6.5 The national system coordinating body will have appropriate mechanisms for consultation, such as the establishment of inclusive advisory bodies and targeted engagement with stakeholders.

6.6 Jurisdictional level coordination (shown in orange on Figure 3) is the responsibility of State and Territory health agencies. This level of coordination will assure the integration of the national approach and its standardised policy, procedures and processes into the existing and planned jurisdictional system.

6.7 Jurisdictional coordination will assist institutions within the State or Territory in their administration and operation of the proposed HoMER enabling system. The structure and administrative arrangements within the health agency enacting jurisdictional coordination varies between the States and Territories.

6.8 Similarly, institutions also have functional responsibility at the jurisdictional level in their administration and operation of the relevant jurisdictional system (shown as shaded orange to purple in Figure 3). Jurisdictional administration and operation is the level where the relevant jurisdictional system's administrative and legislative requirements are operationalised. To do this, institutions are the point of contact for researchers, HRECs and all institutions participating in the proposed national approach by way of the single ethical and scientific review process.

6.9 Typically, the administration of ethical and scientific review processes is the responsibility of an institutional administrator within a Research Ethics Office, a Research Governance Office or a specified individual. In the case of the proposed HoMER enabling system, this function would be situated at the institution where the reviewing HREC resides. To emphasize this key role, this paper refers to the responsible institutional stakeholder as the 'institutional administrator supporting the reviewing HREC'.

6.10 The Institutional level (shown in purple on Figure 3) sitting below jurisdictional level activity shows how researchers, HRECs and institutional administrators oversighting research governance engage with the jurisdictional level.

6.11 Where the research proposal requires specialist scientific expertise to assess research merit and integrity, the reviewing HREC must have access to appropriate expertise to inform its consideration.

6.12 Figure 3 shows how the national, jurisdictional and institutional levels of the proposed national approach interact. Figure 3 does not show specific process steps nor do connections imply the order or sequence for information flows.

6.13 More detail of the key roles and responsibilities of stakeholders can be found in *Part B7 Roles and responsibilities of key stakeholders*.

6.14 Figure 4 shows the process from the perspective of the Principal HoMER Researcher, that is, the process of seeking single ethical and scientific review for a multi-centre research proposal. The flow and type of information that is shared is comparable to information exchanged for single centre research proposals. More detailed discussion of these processes is found in Part C of this document.

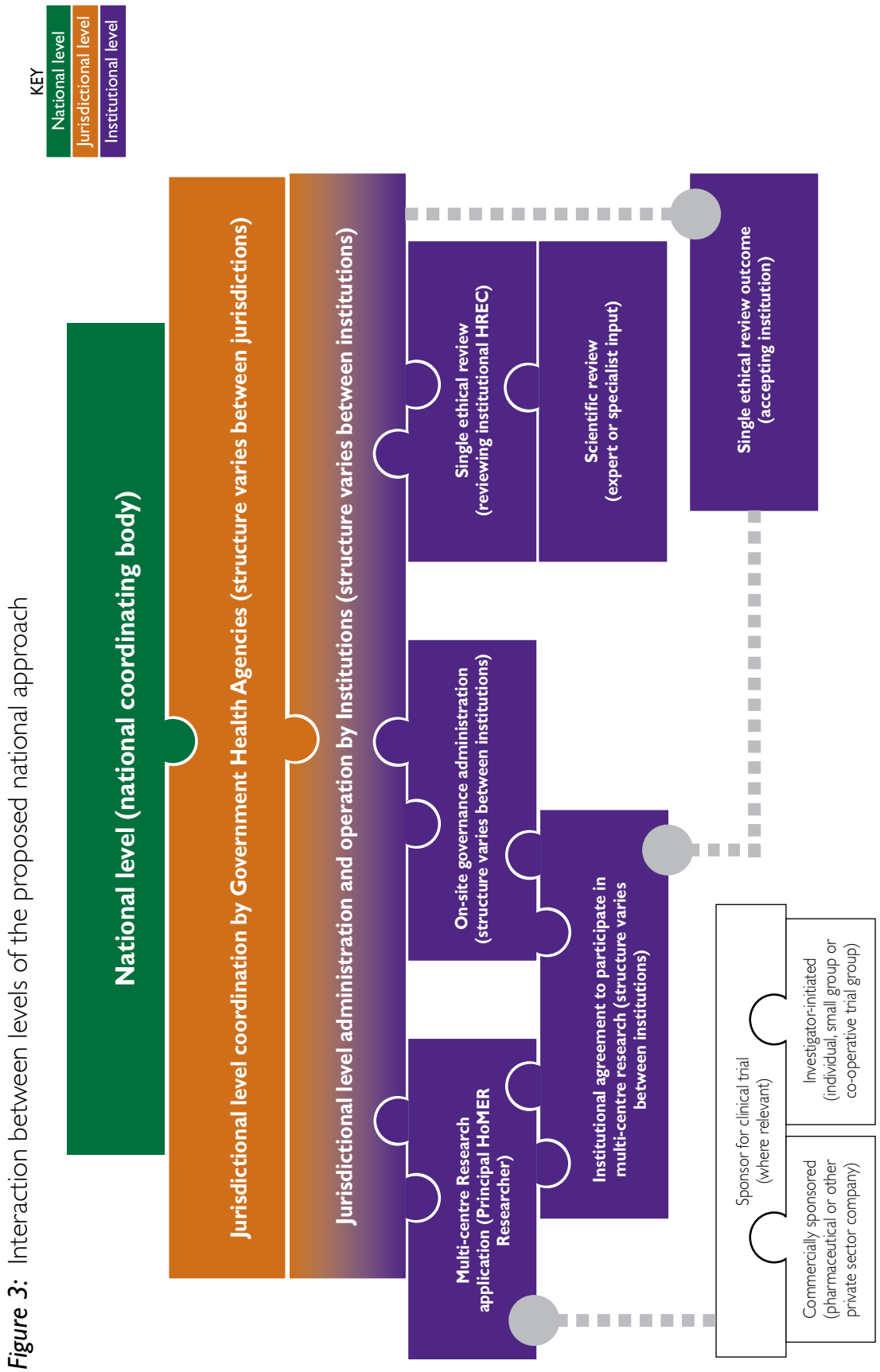


Figure 3: Interaction between levels of the proposed national approach

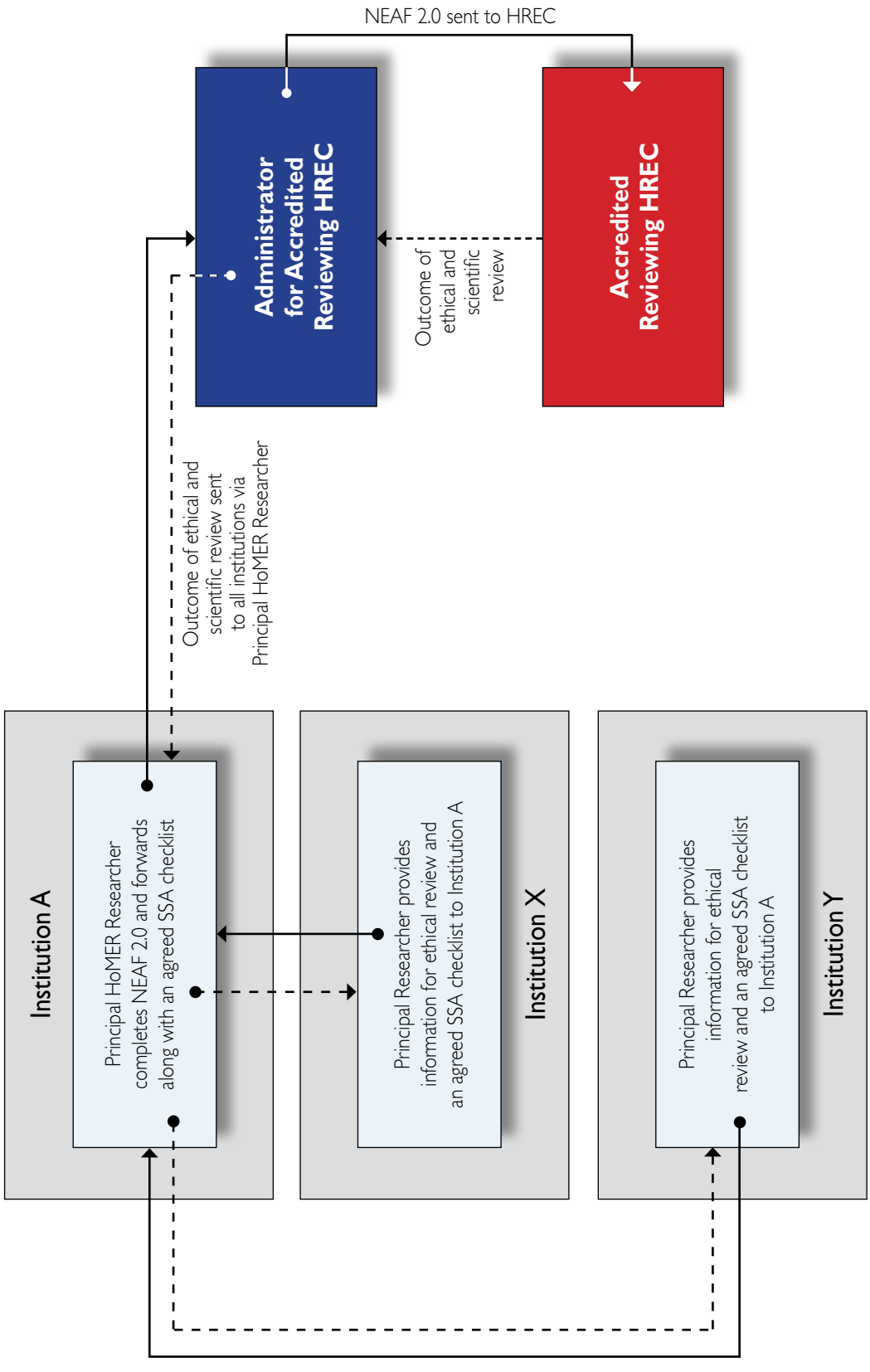


Figure 4: Process for single ethical and scientific review of multi-centre research

6.15 The following features of the proposed HoMER enabling system were identified by jurisdictional focus groups as essential to the proposed national approach:

- clear articulation of the scope and boundaries of the proposed HoMER enabling system
- national guidance on HoMER system enabling processes and procedures
- clear statement of the roles and responsibilities of stakeholders
- flexibility to recognise differing jurisdictional statutory and administrative frameworks
- a national approach to information collection, management and sharing
- accreditation of HRECs acting as the single reviewing HREC
- HREC compliance with standards and processes for single ethical and scientific review
- standard forms for reporting HREC ethical review
- ethical review informed by appropriate scientific expertise
- agreed timelines for all multi-centre health and medical research ethical and scientific processes
- accommodation of low risk research
- guidance on the interface between stakeholders for serious unexpected adverse events for multi-centre clinical trials
- separation of ethical review processes from research governance processes
- consistent processes for managing research governance
- ongoing performance monitoring and management of the proposed HoMER enabling system.

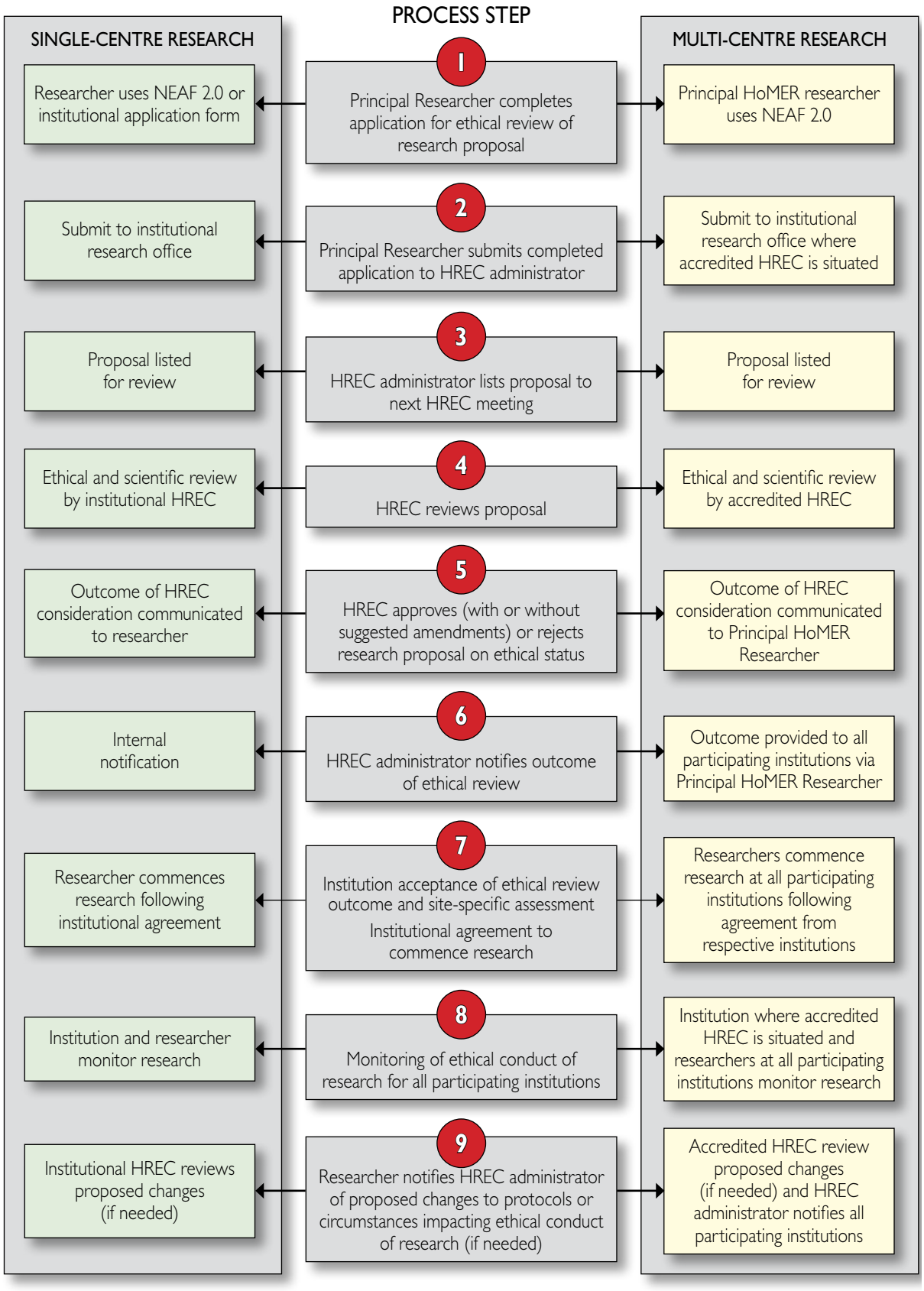
A phased implementation plan and the provision of training of key stakeholders engaging in the proposed national approach were identified as important supporting elements of these features.

6.16 Specific detail of how some features will operate (e.g. information collection and sharing) is under development and will require further consultation.

6.17 While it is recognised that some features are common in ethical and scientific review processes of single site and single institution research, the proposed national standards and standardised procedures and processes will apply only to the single ethical and scientific review in the HoMER multi-centre system.

6.18 Figure 5 shows the flow process for multi-centre ethical and scientific review under the proposed HoMER enabling system compared to the ethical and scientific review of a single centre research proposal. It lays out the responsibilities of institutional stakeholders including the researcher, the HREC administrator, the reviewing HREC and the institution.

Figure 5: Process of ethical and scientific review for single centre research compared with multi-centre research under the proposed HoMER enabling system



Questions:

6A Is the relationship between the three levels of activity represented in Figure 3 clear? If not, what could be done to make the relationship between the three levels of activity clearer?

6B Does the structure identify the correct levels and interaction of administration, operation and coordination? If not, what changes should be made to better identify the levels and the interaction of administration, operation and coordination?

6C Does the structure correctly identify all stakeholders and their roles and responsibilities? If not, what groups of stakeholders are not represented?

6D Is the process and flow of information represented in Figure 4 accurate? If not, what is an accurate process or flow of information?

6E Are there other features of the proposed HoMER enabling system that need to be taken into account as being essential to its structure?

6F Does a process of appeal where ethical approval is not given need to be included?

6G How should differences in jurisdictional statutory and administrative frameworks be addressed in a national approach?

6H Is the process represented in Figure 5 correct for multi-centre ethical and scientific review? If not, what needs to be included and/or removed?

Part B

7 Roles and responsibilities of key stakeholders

7.1 At the three levels of activity shown in Figure 3 in *Part B6 Structure and processes*, different stakeholders will have specified roles and responsibilities. These are discussed below.

National Level Coordination (national coordinating body)

7.2 Responsibilities of national level coordination, in relation to overall policy underpinning the proposed HoMER enabling system, include developing and updating HoMER enabling system policy:

- Accreditation criteria for reviewing HRECs.
- Assess and accredit reviewing HRECs in line with national policy (where relevant).
- A national registry of accredited HRECs.
- A national registry of specialist scientific reviewers.
- Standard for monitoring of accredited HRECs.
- Review and adjust the scope of the HoMER enabling system as needed.
- Standard for evaluating the performance of the national approach.
- Determine the scope for stakeholder training and methodology.
- Roles and responsibilities of key stakeholders.
- A standard for information capture, management and sharing.
- Facilitate communication about the national approach.
- Set agreed timelines for implementation of system features.

7.3 Responsibilities of national level coordination, in relation to policy for ethical and scientific review and research governance processes, include developing and updating policy for ethical and scientific review and research governance within the HoMER enabling system:

- Standard Operating Procedures for the single ethical and scientific review and institutional acceptance.
- A standard for aligning jurisdictional statutory and administrative frameworks.
- Criteria for scientific review (within single ethical review).
- Support the update of the National Statement as needed.
- Support the update of the Code as needed.
- Principles separating research governance from ethical and scientific review.
- Policy on a national approach to indemnity for multi-centre health and medical research.
- The need for a national risk management and indemnity agreement.

7.4 Responsibilities of national level coordination, in relation to HoMER enabling system standard forms and formats, include developing and updating standard HoMER enabling system forms:

- Standard form for reporting of single ethical and scientific review.
- Adopt the standard application form for ethical review (NEAF 2.0).
- Standard form for reporting site governance.
- Content of training modules relevant to operating and engaging with the HoMER enabling system.

Jurisdictional Level Coordination by Government Health Agencies

7.5 Responsibilities of jurisdictional level coordination in relation to HRECs carrying out review, jurisdictional frameworks and information collection, management and sharing:

- assess and accredit reviewing HRECs in line with national policy
- a jurisdictional registry of accredited HRECs
- implement evaluation of national approach at jurisdictional level
- communication on jurisdictional system requirements incorporating the HoMER enabling system
- maintain system for information capture, management and sharing
- communication on jurisdictional statutory and administrative frameworks.

Jurisdictional Level Administration and Operation by Institutions

7.6 Responsibilities of jurisdictional level administration and operation in relation to HRECs carrying out review:

- distribute application for ethical and scientific review, proposed amendments, SAE and SUSAR notices (where applicable) and governance information
- receive complaints regarding ethical conduct of research.

7.7 Responsibilities of jurisdictional level administration and operation in relation to institutions accepting review outcome:

- distribute outcome of single ethical review and amendments to accepting institutions via Principal HoMER Researcher
- distribute SAE and SUSAR notices (where applicable).

7.8 Responsibilities of jurisdictional level administration and operation in relation to system maintenance:

- adopt policy and standard forms of national approach.

7.9 Responsibilities of jurisdictional level administration and operation in relation to information collection, management and sharing:

- operate system for information capture, management and sharing.

7.10 Responsibilities of jurisdictional level administration and operation in relation to training:

- deliver training.

7.11 Responsibilities of jurisdictional level administration and operation in relation to monitoring of multi-centre research project:

- monitor reviewing HREC compliance with accreditation criteria
- monitor delivery of information against agreed timelines.

7.12 Responsibilities of jurisdictional level administration and operation in relation to jurisdictional frameworks:

- assure compliance with jurisdictional statutory and administrative frameworks.

Institutional Level (institutional users of the jurisdictional system)

7.13 Responsibilities of institutional users in relation to institutional engagement:

- determine whether HREC will be nominated for accreditation
- determine whether research will be conducted on site.

7.14 Responsibilities of institutional users in relation to single ethical and scientific review:

- Reviewing HRECs:
  - carry out single ethical and scientific review of multi-centre health and medical research proposal
  - access appropriate scientific expertise
  - monitor research including SAE and SUSAR notices (where applicable) and need for amendment
  - receive and consider complaints regarding ethical conduct of research.
- HRECs situated in accepting institutions:
  - register outcome of single ethical review.

7.15 Responsibilities of institutional users in relation to on site research governance:

- provide information (where relevant) regarding on site research governance matters to administrator for reviewing HREC.

7.16 Responsibilities of institutional users in relation to multi-centre research applications for ethical and scientific review:

- provide review application on standard form
- meet agreed timelines for delivery of information to administrator supporting reviewing HREC
- manage information including SAE and SUSAR notices (where applicable).

Reviewing HREC and Accepting Institution

7.17 Responsibilities of the reviewing HREC that align with existing ethical review processes:

- carry out single ethical and scientific review of multi-centre health and medical research proposal
- access appropriate scientific expertise
- monitor research including SAE and SUSAR notices (where applicable) and need for amendment.

7.18 Responsibilities of the accepting institution:

- receive outcome of single ethical and scientific review and adopt its recommendations on-site
- report change to on-site governance arrangements (where relevant) to the administrator supporting the reviewing HREC
- receive and consider complaints regarding ethical conduct of research at all sites where research is carried out
- alert administrator supporting the reviewing HREC of jurisdictional statutory and administrative framework differences impacting acceptance for inter-jurisdictional research.

7.19 The reviewing HREC does not have responsibility for matters of institutional research governance other than where there is an interface of governance considerations with the ethical assessment of the multi-centre research proposal.

7.20 Similarly a reviewing HREC approval of a research proposal as being of an appropriate ethical standard does not constitute agreement by an accepting institution that the research can be carried out on-site.

7.21 The autonomy of each institution to decide whether or not to participate in a specific multi-centre research project is respected. If the institution chooses to participate, then the proposed national approach relevant to the specific research project will apply to the institution and its HREC (e.g. compliance with agreed responsibilities including monitoring and reporting obligations).

Principal HoMER Researcher

7.22 The researcher, nominated as the Principal HoMER Researcher for the multi-centre research proposal, will follow the application process to submit the research proposal for the single ethical and scientific review, as well as taking responsibility for monitoring and reporting standards including:

- providing the ethical review application on NEAF 2.0
- distributing the outcome of single ethical and scientific review to accepting institutions
- meeting agreed timelines for delivery of information to administrator supporting the reviewing HREC
- managing information including SAE and SUSAR notices (where applicable).

7.23 Where the proposed multi-centre research is a commercially sponsored clinical trial of an unapproved therapeutic good (e.g. by a pharmaceutical company or another private sector company), the responsibilities of the Principal HoMER Researcher within the proposed national approach are the same as for commercially sponsored clinical trials conducted outside of the proposed HoMER enabling system.

Research Governance

7.24 The institution will manage on-site research governance responsibilities and retain its right to determine whether or not to participate in a specific research project as well as when research will commence.

7.25 Within the proposed HoMER enabling system, the nominated body or individual within an institution with responsibility for research governance matters will:

- provide information (where relevant) regarding on-site research governance matters to the administrator supporting the reviewing HREC.

7.26 The administrator supporting the reviewing HREC, in turn, will provide on-site governance information to the reviewing HREC.

Questions:

7A Generally speaking, what is your understanding of the role and responsibility of a coordinator within the proposed HoMER enabling system? Of an administrator?

7B Can the roles and responsibilities of stakeholders in the proposed national approach be made clearer? If so, how?

7C What additional roles and responsibilities of stakeholders should be included, if any?

7D Are you aware of any areas of conflict between the proposed roles and responsibilities of stakeholders and the roles and responsibilities of stakeholders in existing State and Territory arrangements? If so, what is the conflict and what changes would be needed to the proposed roles and responsibilities?

7E What would you see the role and responsibility of NHMRC to be after implementation, if any?

Part C Operation of the proposed HoMER enabling system

8 Ethical and scientific review

8.1 A fundamental feature of the proposed HoMER enabling system is the conduct of a single ethical and scientific review in the place of multiple reviews of health and medical research carried out at multiple centres across and/or within jurisdictions.

8.2 Both the research and the single ethical and scientific review will be carried out following guidance applicable to all Australian health and medical research:

- The National Statement – content and conduct of ethical review.
- The Code – responsible conduct of research.

8.3 The implementation of the proposed HoMER enabling system through existing and planned jurisdictional systems does not remove the autonomy of an institution to determine whether a multi-centre health and medical research proposal, subjected to a single ethical and scientific review, will be conducted at sites under its control.

8.4 Institutions should be aware of jurisdictional administrative arrangements prescribing their participation in an existing or planned jurisdictional system of ethical and scientific review processes (e.g. public sector institutions).

8.5 The single ethical and scientific review will be carried out by a HREC that has been assessed and accredited under the proposed national approach (*Part C9 Scheme to review and recognise Human Research Ethics Committees*).

8.6 The reviewing HREC and its host institution will utilise standardised forms and follow agreed ethical and scientific review policies, procedures and processes. Similarly, institutions must comply with agreed process timelines (*Part C12 Timelines for processes*).

Submission of a multi-centre health and medical research proposal for single ethical and scientific review

8.7 It is suggested the process for submission of a multi-centre health and medical research proposal for single ethical and scientific review will follow a pathway being:

- The Principal HoMER Researcher will submit the multi-centre health and medical research proposal to the HREC located at their institution if that HREC is an accredited reviewing HREC.
- If the HREC located at the institution of the Principal HoMER Researcher is not accredited, the Principal HoMER Researcher will submit the multi-centre health and medical research proposal to an accredited reviewing HREC located at one of the institutions participating in the research.
- If none of the HRECs located within the group of institutions participating in the research is accredited, the Principal HoMER Researcher will seek the name of a suitable accredited HREC from the jurisdictional registry for accredited HRECs within their jurisdiction.
- If the multi-centre health and medical research proposal requires specialist expertise that does not exist within any HREC within their jurisdiction, the Principal HoMER Researcher will seek the name of a suitable accredited HREC from the national registry for accredited HRECs. (*see Part C13 The impact of the proposed national approach on specific types of research*).

8.8 The suggested pathway for determining the submission of a multi-centre health and medical research proposal outlined above is intended to support easy access between the Principal HoMER Researcher and the reviewing HREC. It will distribute the workload of ethical and scientific review amongst accredited HRECs and recognise the need for a fall back position in the event that an institutional HREC within the multi-centre research group is not accredited.

Scientific review

8.9 It is the responsibility of the reviewing HREC to ensure it has access to appropriate scientific expertise to consider the multi-centre health and medical research proposal. If the appropriate scientific expertise is not available at the institution where the single ethical and scientific review is carried out, the reviewing HREC (through its administrative support) must identify where such expertise can be accessed.

8.10 There may be some areas of scientific expertise that could benefit from central coordination, for example, where scientific expertise is needed in reviewing research involving emerging technology.

8.11 NHMRC will investigate the need for establishing panels of specific scientific expertise that may be utilised by accredited HRECs. As a first step, criteria outlining when specialist scientific expertise is needed will be developed.

Standard Operating Procedures for the conduct of ethical and scientific review

8.12 The need for SOPs for the conduct of ethical and scientific review within the proposed HoMER enabling system has been identified. The scope and format for SOPs have not yet been developed (*Part C11 Standardisation of forms*) and will be subject to targeted consultation of key stakeholders.

Process for accepting a single ethical and scientific review

8.13 The institutions participating in the multi-centre research will accept the outcome of the single ethical and scientific review without re-review by their institutional HREC. The detail of information provided by the administrator of the reviewing HREC to the accepting institutions (via the Principal HoMER Researcher) is yet to be developed, but must reflect the research governance arrangements specific to each site.

Monitoring of a multi-centre health and medical research proposal during its conduct

8.14 It is suggested the process for monitoring the ethical conduct of the multi-centre research project is as follows:

- The institution of the reviewing HREC will be responsible for monitoring of the research at all sites. Administrative processes supporting this responsibility will be negotiated by the multi-centre research group and align with the institutional research governance arrangements at all sites.
- The institution of the reviewing HREC will be responsible for managing the investigation of complaints associated with the ethical conduct of research at all participating sites where the research will be conducted.

Comment on administrative processes linked to the conduct of a single ethical and scientific review

8.15 NHMRC recognises that institutions have different costing and fee schedules for the conduct of ethical and scientific review and assessment of site specific research governance arrangements. In some instances, there may be no fee charged for the ethical and scientific review of research.

8.16 Where it is the practice that costing and fees are levied for the single ethical and scientific review of a multi-centre health and medical research proposal, the determination of costing and fees will be subject to national guidance. Such guidance will be developed and will be informed by the final structure of the proposed national approach and through NHMRC consultation with key stakeholders.

8.17 Chapter 5.1 of the National Statement provides for alternative ethical assessment processes for low risk research. However, as alternative processes may vary between institutions, low risk multi-centre health and medical research under the proposed HoMER enabling system will require a single ethical and scientific review process by an accredited reviewing HREC.

Questions:

8A It is proposed that the reviewing HREC, in the first instance, should be the HREC of the institution where the Principal HoMER Researcher is located. Is this appropriate? If not, why not?

8B Is there a need for establishing panels of specific scientific expertise that may be accessed by reviewing HRECs? What areas of specific expertise should be included in such panels?

8C Are there other types of expertise (other than scientific) that should have expert panels established?

8D Should the institution where the reviewing HREC is located have sole responsibility for monitoring the progress of the research at all sites where it is conducted? If not, why not?

8E Should there be national guidance in relation to the costing and fees set by institutions for ethical and scientific review? For assessment of site specific arrangements related to research governance? What should such guidance include?

8F Should there be national guidance in relation to costing and fees for ethical and scientific review under the proposed national approach? If so, what would be the scope of such guidance?

Part C

9 Scheme to review and recognise Human Research Ethics Committees

9.1 The detail of the proposed accreditation scheme for reviewing HRECs is under development. NHMRC will be engaging key stakeholders, including State and Territory agencies, institutional administrators, HREC members and Chairs, researchers and the Australian Health Ethics Committee, in the development of the accreditation criteria early in 2009.

9.2 The proposed HoMER enabling system utilises the ethical and scientific review of a single HREC, also termed 'the reviewing HREC'. The outcome of the single ethical and scientific review is sent to all institutions participating in the multi-centre health and medical research proposal. These institutions are also termed as 'accepting institutions'.

9.3 The roles and responsibilities of the reviewing HREC and its administrative office is found in *Part B7 Roles and responsibilities of key stakeholders*. The proposed scheme to review and recognise HRECs, termed 'accreditation', applies to reviewing HRECs carrying out the single ethical and scientific review of multi-centre research proposals and not to any other HREC that may be located within accepting institutions.

9.4 The proposed HoMER enabling system is based on a single ethical and scientific review being conducted by a HREC according to the National Statement. To assure accepting institutions that the quality and adequacy of a single ethical and scientific review process is equivalent to that of their institutional HREC, a scheme to 'review and recognise[1], the reviewing HREC is fundamental to the proposed HoMER enabling system.

9.5 The accredited reviewing HRECs will need to meet specified criteria applying to their review practices and the practice of their auspicing institution. Similarly, the auspicing institution will need to demonstrate its commitment and support for ethical review activities. For this reason, the institution, rather than the HREC, will nominate the HREC to be assessed for accreditation.

9.6 While still under consideration, some probable features of the scheme are listed below:

- The scheme will only apply to institutional HRECs nominated by their auspicing institution.
- Nominated HRECs will need to be assessed against specified criteria.
- Accreditation will only be given to HRECs that demonstrate their processes and practices follow those of the HoMER enabling system and relevant jurisdictional administrative arrangements.
- The accreditation scheme will be uniform across Australia and an accredited HREC in one jurisdiction will be accredited in all jurisdictions.
- Assessment of a nominated HREC will involve institutional signoff (statement of claims) and an independent assessment by a panel of appropriately qualified experts (this may involve both desktop review and/or site visits).

1 The phrase 'review and recognise' was used by the Australian Health Ministers' Advisory Council to describe the assessment process of HRECs within the proposed HoMER enabling system. This document will use the term 'accreditation' to refer to 'review and recognition' of reviewing HRECs.

- Claims made in support of accreditation must be verifiable through evidence or observation.
- A public registry of accredited reviewing HRECs will be established and maintained.

9.7 Institutions may choose to not nominate their institutional HREC for accreditation within the proposed HoMER enabling system for several reasons:

- Researchers within the institution are not expected to be the Principal HoMER Researcher for multi-centre health and medical research.
- The number of multi-centre research proposals historically considered by the institutional HREC does not meet minimum frequencies (to be determined) to adequately demonstrate compliance with the accreditation scheme's criteria.
- Research governance arrangements within the institution do not support a need for the institutional HREC to be accredited.

9.8 An institution should be aware of any jurisdictional system requirements or contractual requirements when considering whether or not to nominate its HREC for accreditation.

9.9 HRECs of institutions that do not participate in the review of multi-centre research proposals within the proposed HoMER enabling system do not require accreditation. The absence of accreditation should not be viewed as a judgment of the competency of an institutional HREC to carry out ethical and scientific review.

9.10 It is anticipated some institutional HRECs nominated for accreditation may not sufficiently meet the accreditation scheme criteria, that is, additional information or actions may be required before the assessment of the HREC to be accredited as a reviewing HREC is successful. Failure to achieve accreditation means the institutional HREC may not act as a reviewing HREC within the proposed HoMER enabling system. There is no sanction for either the institution or its HREC should accreditation not be achieved.

9.11 The governance of the accreditation scheme reflects that it is intended to be both national in its coverage and uniform in its execution. Assessment processes will be standardised and, it is anticipated, local expertise will be utilised. A registry of accredited reviewing HRECs will be established.

Questions:

9A Is the word 'accreditation' suitable to describe the process for an HREC to be recognised as suitable to act as the reviewing HREC? If not, why not?

9B Given that further consultation on the accreditation scheme will take place, what do you believe the scheme should include?

9C What incentives (or disincentives) do you see for an institution in considering whether or not to nominate its HREC for accreditation?

Part C

10 Research Governance

10.1 Within the proposed HoMER enabling system, differentiating research governance and research ethics (i.e. ethical and scientific review) activities will be strengthened to the extent that the national approach will define the roles and responsibilities of key stakeholders.

10.2 Such a differentiation will minimise the current practice where HRECs make decisions on research governance arrangements outside of those matters relevant to the ethical review of research proposals.

10.3 In general, research governance includes the mechanisms by which institutional administrators and researchers:

- share responsibility and accountability for research conduct and outcomes
- ensure that research complies with relevant institutional policy and legislation
- implement the principles of risk management during the life of the research project
- monitor the progress of and improve the quality of their research.

10.4 The single ethical and scientific review process will accommodate the institutional research governance frameworks of the institutions participating in multi-centre health and medical research by:

- ensuring the institution's responsibility for research governance and accountability for its site is maintained
- establishing appropriate monitoring processes.

10.5 The single ethical and scientific review may also identify new or additional institutional risks due to the research being conducted at multiple sites that will need management at institutional level.

10.6 The NHMRC/ARC/Universities Australia *Australian Code for the Responsible Conduct of Research* (2007) (the Code) sets out the institution's responsibility for establishing good governance and management practices that, in turn, will encourage responsible conduct by researchers. The Code describes the institution's responsibility to manage research governance (Section 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."

A special reference to collaborative research across institutions is made in Section 8 of the Code.

10.7 The guidance on research governance in the Code, as well as the guidance on research governance in the National Statement, applies to both single and multi-centre health and medical research.

10.8 An example of a simple institutional research governance framework could include:

Stage	Component	Actions required
Before research begins	Initial site-specific assessment	• Confirmation of 'fit' within the strategic priorities and plans of the institution. • Definition of roles, responsibilities and accountabilities of all participants (including researchers, HRECs and patients). • Confirmation that the institution has appropriate facilities and is appropriately staffed. • Confirmation of any conflict of interests. • Preparation and review of risk management strategies.
	Financial accountability	• Confirmation of appropriate budget.
	Insurance issues	• Establishment of appropriate indemnity and/or insurance coverage.
	Legal and administrative issues	• Ethical and scientific approval has been given. • Compliance with all guidelines, regulations, legislation and codes of practice (state and federal). • Standardisation and review of contractual and other legal documentation. • Defined agreements for any research collaborations. • Completion of grants processes. • Determination of fees (if applicable).
	Credentialing	• Confirmation that staff have appropriate qualifications and experience. • Confirmation of supervision and mentoring of student/junior researchers.
	Intellectual property	• Protection for the institution's IP. • Clarity about authorship and publication.
During research	Monitoring	Policies, procedures and protocol relating to: • Data management and storage. • Quality control (including supervision of staff and record-keeping). • Training and mentoring of student/junior researchers. • Safety of all research participants. • Privacy and confidentiality of research data. • Risk management strategies. • Financial management and budgeting. • Ethical conduct via coordination with HREC. • Alleged research misconduct, including complaints. • Self-audit and externally-evaluated programs regarding good research practice guidelines. • Compliance with internal and external reporting obligations.
After research is completed	Closure	• Ensuring the study closure is orderly and systematic. • Providing information to participants where required. • Confirmation of record storage (including future destruction). • Establishing an audit of ongoing research (if applicable).

Indemnity and insurance issues related to the proposed HoMER enabling system

10.9 Early consideration of the essential features of the proposed national approach suggested a national guidance on indemnity and/or a national risk management and indemnity agreement may be necessary to promote consistency between jurisdictional systems. Further consideration of how this is to be achieved will be subject to targeted consultation.

Questions:

10A What research governance activities should be included in a site specific assessment within the proposed HoMER enabling system?

10B What research governance activities require ethical consideration?

10C Does a single ethical and scientific review process of multi-centre health and medical research introduce additional risks over a single centre ethical and scientific review process? If so, what risks and how would they need to be managed?

10D Considering the example framework presented for research governance, are there other components that should be included?

Part C

11 Standardisation of forms

11.1 In order to facilitate a national approach, standardised policies, procedures and processes may be necessary. The standardisation of forms will assist with reducing duplication of effort across jurisdictions and will help define the explicit difference between on-site research governance and ethical and scientific review of research projects.

11.2 Standardised forms in the proposed HoMER enabling system will establish uniformity across jurisdictional systems and would include, but not be limited to, the following:

- A National Ethics Application Form (NEAF 2.0) – used to submit a research proposal for ethical and scientific review.
- A Single Ethical Review Reporting Form – used by the reviewing HREC to report the outcome of the ethical and scientific review (to be developed).
- Site Specific Assessment Form – used to ensure on-site governance procedures are reported in a standardised format across jurisdictions (to be developed).
- Letters to researcher(s) requesting further information, requesting a progress report, requiring amendment to the research protocol – used to inform the Principal HoMER Researcher and collaborative researchers of required process updates.

11.3 The proposed HoMER enabling system will not prevent existing and planned jurisdictional systems or institutions from utilising standard forms for specific types of research (e.g. Medicines Australia's Clinical Trials Agreement).

11.4 Guidance to standardise the format and layout other forms has also been suggested and includes:

- patient information and consent forms (to be developed)
- conduct of ethical and scientific review (to be developed).

Information capture and sharing

11.5 The standardisation of forms would facilitate the development and adoption of a national tool to capture and share information. Consideration will be given to the electronic submission of the standardised forms to reduce timelines within the ethical and scientific review process *(Part C12 Timelines for processes).*

11.6 NHMRC will engage with key stakeholders to develop and trial standardised forms and national tools to collect and share information.

Questions:

11A What other forms, if any, need to be standardised within the proposed HoMER enabling system?

11B Is it appropriate to standardise patient information and consent forms? If not, why not? If so, in what way?

11C Should the function of an information capture tool be limited to ethical and scientific review processes? If not, what other functionality should such a tool have?

Part C

12 Timelines for processes

12.1 Within the proposed national approach, processes of ethical and scientific review would operate under specified timelines.

12.2 There are different timelines operating in the existing jurisdictional systems. An example of a typical process timeline used in existing jurisdictional systems follows:

- The total time allocated to completing the process of ethical and scientific review is 60 days.
- A HREC should hold at least 10 scheduled committee meetings a year for the purpose of ethical review of applications. Additional meetings may be scheduled where necessary to ensure that an ethical opinion on the research proposal is given within the 60-day time limit.
- If further information is required to give an opinion on a research proposal the request must be in writing and within 10 working days of the HREC meeting. The 60-day period to process the application is suspended from the date on which the request for further information was sent to the applicant. The 'clock' will start again when a complete response is received.
- Minutes of the HREC meeting are made available within a determined number of working days following the meeting.
- Applicants and collaborative institutions receive notification of the outcome of the single ethical and scientific review within 10 working days from date of decision.

12.3 Outside of ethical and scientific review, other processes may also operate according to specified timelines. For example:

- The time for assessment and approval of an institutional HREC to act as the reviewing HREC is within four weeks of receipt of a correctly completed application.
- Notice of assessment (e.g. site visit) to an institutional HREC applying to be a reviewing HREC is at least two weeks.
- Progress reports on the ethical status of research are tabled at least annually or more frequently as directed by the reviewing HREC. Amendments and notices of any changes impacting the ethical status of the research project, including receipt of complaints of ethical misconduct or changed status, are received by the reviewing HREC within five working days.

Questions:

12A How appropriate are the suggested timelines? Should the 60 days be 'working' days or 'calendar' days?

12B When should the 60 days for the process of ethical and scientific review start?

12C Are there any other process steps within the single ethical and scientific review that need to have a specified timeline?

12D What should be the response if timelines are not adhered to?

Part C

13 The impact of the proposed national approach on specific types of research

13.1 Particular types of research and research involving specific participants within the proposed HoMER enabling system are discussed below.

Research on unapproved therapeutic goods

13.2 In Australia, the Therapeutic Goods Administration regulates clinical trials involving unapproved therapeutic goods (*Part A3 Regulatory and administrative frameworks*).

13.3 In addition, some jurisdictional systems have policies and processes that impact on clinical trials carried out within the public health system. These processes may impose obligations on researchers conducting clinical trials. For example, there may be mandatory jurisdictional policies and protocols that apply. These can range from requiring the use of standardised forms and contracts to prescribing standards for scientific review of clinical trials to specifying obligations in research governance areas such as insurance coverage.

13.4 Obligations placed on researchers conducting clinical trials across and/or within Australian jurisdictions would not change from existing arrangements although there may be a greater need to ensure mechanisms for effective communication and information dissemination are in place.

13.5 The NHMRC Australian Health Ethics Committee published *Advice for HRECs on adverse event reporting in Australia in clinical trials* (Alert No 1, 18 April 2007) that sets out guidance on the responsibilities of institutions and HRECs in relation to reports of serious adverse events or serious adverse reactions occurring in clinical trials for which institutions are responsible and that HRECs have reviewed and given ethical approval. The management of information dissemination of clinical trials to HRECs in the proposed national approach will comply with this alert (and any revisions of this alert).

Research involving Aboriginal and Torres Strait Islander Peoples as participants

13.6 NHMRC has published two guidelines in relation to health and medical research involving Aboriginal and Torres Strait Islander People participants:

- *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003).
- *Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (2006).

13.7 *Values and Ethics* comprise background information and details the six values and ethics that form the core component of the guidelines, which are:

- Reciprocity
- Respect
- Equality
- Responsibility
- Survival and protection
- Spirit and Integrity

13.8 Similar to research conducted at single sites, multi-centre health and medical research within the proposed HoMER enabling system will comply to these guidelines as described in Chapter 4.7 *Aboriginal and Torres Strait Islander Peoples* of the *National Statement on Ethical Conduct in Human Research* (2007). This means the ethical and scientific review (carried out by the reviewing HREC) must include an assessment by or advice from:

- People who have networks with Aboriginal and Torres Strait Islander Peoples and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples of all sites where the research is proposed to be carried out.
- People familiar with the culture and practices of the Aboriginal and Torres Strait Islander Peoples with whom participation in the research will be discussed.

13.9 The reviewing HREC will need to be aware of any additional jurisdictional system requirements relating to research involving Aboriginal and Torres Strait Islander Peoples.

Research classified as 'low risk'

13.10 The National Statement Chapter 2.1 *Risk and Benefits* defines 'low risk research' as research in which the only foreseeable risk is one of discomfort and provides guidance to HRECs and institutions on the assessment of risk against possible benefit from the research proceeding.

13.11 In line with the National Statement, institutions may have a local approach for establishing an ethical review process for research that is assessed as low risk that includes an ethical assessment without a HREC review. Within the proposed HoMER enabling system all research, even if categorised as 'low risk', will be subject to a single ethical and scientific review conducted by an accredited reviewing HREC.

Questions:

13A There are three types of research included here. What other specific types of research need special consideration in the proposed national approach, if any?

13B What specific issues need to be considered in the proposed HoMER enabling system in relation to health and medical research involving Aboriginal and Torres Strait Islander Peoples?

13C How could these issues be addressed to facilitate the proposed HoMER enabling system being used for multi-centre health and medical research involving Aboriginal and Torres Strait Islander Peoples?

13D Is the suggested requirement for all multi-centre 'low risk' research to undergo an ethical and scientific review by an accredited reviewing HREC reasonable? If not, why not?

Part D Maintenance of the proposed HoMER enabling system

14 Performance of the proposed national approach

14.1 To ensure the proposed national approach is operating in an effective and efficient manner, monitoring of the performance of the proposed national approach will need to be integrated into existing and planned jurisdictional systems.

Monitoring the ongoing implementation of the proposed national approach

14.2 The proposed national approach will be monitored against yet to be established national performance targets. Key Performance Indicators (KPI's) against defined standards for effectiveness and efficiency will need to be developed.

14.3 Performance monitoring will provide for continuous improvement of the proposed national approach *(Part D15 Continuous improvement)* and will highlight areas where compliance to the proposed HoMER enabling system processes and procedures is problematic.

14.4 Typically, compliance is assessed through both self and independent audits. Guidance on self audit is yet to be developed. NHMRC will engage with and consult key stakeholders to develop and trial, where necessary, guidance material developed on system auditing.

14.5 Activities subject to audit may include, but are not limited to:

- compliance with SOPs
- use of standardised forms
- research governance arrangements
- amendments of research protocols due to unexpected events
- approach to acceptance of single ethical and scientific review processes
- information capture, tracking and transfer between jurisdictions
- conduct of ethical review, including application of criteria when specialist scientific expertise is required.

Complaints mechanisms as a measure of system performance

14.6 Mechanisms for managing complaints, including allegations of non-compliance, in relation to the proposed HoMER enabling system's operation are yet to be developed. Similarly, appeals against 'findings' of non-compliance must be accommodated.

Questions:

14A What areas of the proposed national approach need to be measured (i.e. require Key Performance Indicators to be developed)?

14B What are your suggestions for Key Performance Indicators?

14C What should be the response if the targets described in Key Performance Indicators are not met?

14D Who would have responsibility for managing complaints and appeals about the implementation of the national approach (please include the nature of complaints and appeals in your discussion)?

14E Who should have responsibility for conducting compliance audits of institutional practice (as needed)?

14F What should be the response if an audit discovers evidence of non compliance?

Part D

15 Continuous Improvement

15.1 The implementation of the proposed HoMER enabling system will involve significant time, effort, resources and coordination across jurisdictions. Ongoing systematic and objective assessment (evaluation) of the proposed national approach will assess the appropriateness, effectiveness and efficiency of adopted policies, procedures and processes.

15.2 Evaluation will support and enhance the overall performance of the proposed HoMER enabling system by providing information that can be used to facilitate ongoing improvement. Assessment of compliance to Key Performance Indicators (the targets against which monitoring will occur) will also drive further system enhancements.

15.3 The timing of evaluation activities will affect the way that the evaluation is conducted. For example, quality reviews during implementation will add value to the iterative development of proposed HoMER enabling system features. Monitoring against Key Performance Indicators, for example, during planned pilots of processes and procedures will provide an assessment of implementation across sites. Regular evaluation after the full implementation of the proposed national approach will highlight processes and procedures needing refinement.

15.4 The management of the evaluation and review of the proposed national approach will require coordination at the national level. The national coordinating body will develop guidance material, in consultation with key parties and jurisdictions, to support the continuous improvement of the proposed HoMER enabling system.

15.5 Evaluation activities will include consideration of how consistency is maintained for proposed HoMER enabling system processes, and the impact of revising national guidelines, such as the National Statement and the Code.

Questions:

15A Who should have responsibility for evaluating the effectiveness and efficiency of the proposed national approach?

15B What mechanisms, other than evaluation, should be used to ensure the proposed HoMER enabling system is continually improving?

15C When and how frequently should the proposed HoMER enabling system be formally evaluated?

Part D

16 Training of key stakeholders

16.1 As the implementation of the proposed national approach will involve the introduction of new or revised policies, procedures and processes, it is anticipated key stakeholders may require 'training' to effectively operate relevant administrative processes.

16.2 The detail of what training may be required and how training may be delivered is under development. NHMRC will carry out a training needs analysis of key stakeholders, including consideration of appropriate methods of delivery. NHMRC will consult with jurisdictions and key stakeholders on the design and development of relevant guidance material for stakeholders in the national approach.

16.3 Where possible consideration should be given to aligning the training activities of key stakeholders in the proposed HoMER enabling system processes, with existing training programs organised by jurisdictional and/or institutional coordinators.

16.4 Demonstrated institutional commitment to ongoing professional development has been flagged as a possible criteria for accreditation of reviewing HRECS *(Part C10 Scheme to review and recognise Human Research Ethics Committees).*

Questions:

16A What is your understanding of 'training'?

16B Who should be 'trained' in the proposed HoMER enabling system processes?

16C What methods could be used to ensure relevant stakeholders understand the proposed national approach?

16D Who should be responsible for 'training'?

Part E Supporting documents

Appendix A Existing jurisdictional systems

The approach of states and territories to streamline ethical review processes is discussed in *Part A4 Existing jurisdictional approaches*. Models of existing jurisdictional systems follow.

Australian Capital Territory

ACT Health has four primary areas of cooperation aimed at enhancing health and medical research endeavours within the ACT:

- Supporting the development of the health and medical research community in the ACT and surrounding region in a way that builds on the ACT's local advantages; including planning for the coherent development of research facilities, communication technology, training in research and major research collaborations.
- Ensuring a whole of government approach that coordinates the evolution of the ACT's health and medical research effort with industry development and commercial investment.
- Pursuing the ACT's interests in the development of national health and medical research policy and playing a strong part in the implementation of that agenda on behalf of the nation.
- Encouraging policy and practice oriented research by the health and medical researchers; and supporting research and evidence based policy and practice in the provision of health care.

In addition, ACT Health has formed a collaborative working group with the ACT Health and Medical Research Council, the Australian Catholic University and the University of Canberra to pilot a mentoring program for allied health researchers in the ACT.

New South Wales *(Figure 6)*

In 2007, a system of single ethical and scientific review of multi-centre research was implemented with the aim that every research project conducted within the NSW public health system is scientifically and ethically reviewed once only.

Lead Human Research Ethics Committees (HRECs) are accredited to conduct a single ethical and scientific review of multi-centre research on behalf of all sites within the NSW public health system at which a research project is to be conducted, thereby eliminating the need for each local HREC to conduct its own review. Public health organisations retain responsibility for authorising the commencement of research within their institutions.

As such, public health organisations are required to undertake a site-specific assessment of each research project, thereby allowing the organisation to consider whether it has the capacity to conduct the research at that site. This site-specific assessment considers such matters as staff, resources and patient availability.

The site-specific assessment and ethical review may occur in parallel, however the decision to authorise or not authorise the conduct of a research project is only made by the public health organisation when the lead HREC has granted approval and the site-specific assessment has been satisfactorily completed.

All multi-centre research projects conducted within the NSW public health system must be reviewed under the single ethical review system by a lead HREC.

Exceptions to the single review process

In NSW there are three types of exception to the single review process:

- Research projects involving persons in custody in NSW must be submitted to the HREC of NSW Justice Health, even if the project has been reviewed by a lead HREC.
- Research projects coming within section 6.4 of the NSW Aboriginal Health Information Guidelines (currently under review) must be considered for review by the HREC of the Aboriginal Health and Medical Research Council, even if the project has been reviewed by a lead HREC.
- Research projects requiring access to statewide data collections owned or managed by NSW Health must be reviewed by the NSW Population & Health Services Research Ethics Committee (a HREC jointly convened by NSW Department of Health and the Cancer Institute NSW). This HREC is a lead HREC so although research projects must be reviewed by this committee, further review by another lead HREC is not required.

HREC status

HRECs must be nominated for accreditation by the public health organisation's Chief Executive, with the support of the HREC Chair. Applications for accreditation are assessed against a set of accreditation standards by a selection panel convened by the Chief Health Officer of NSW. All HRECs that meet the accreditation standards are accredited as lead HRECs.

Types of Lead HRECs

A HREC may be accredited as a lead HREC in one or both of the following categories:

- Clinical trials/interventional clinical research.
- General research (which includes epidemiological research, population health research, health services research, qualitative research, clinical research of a non-interventional nature and other general categories of research).

In addition, a few HRECs operate in specialised therapeutic areas. For example, the Cancer Institute NSW Clinical Research Ethics Committee will accept cancer related research only.

Submission options

Applications can be submitted to any NSW Health lead HREC, provided that the HREC is accredited in the research area of the project. For example, clinical trials must be submitted to a lead HREC accredited in clinical trials/interventional clinical research. In addition, if the lead HREC operates within a specialised therapeutic area, only research in that therapeutic area may be lodged with that HREC. Where possible, the application should be submitted to a lead HREC associated with one or more of the sites at which the research is to be conducted.

Northern Territory *(Figure 7)*

There are two Human Research Ethics Committees sponsored by the NT Department of Health and Families operating in the Northern Territory, one for Central Australia and one for the Top End.

These committees operate in accordance with the *National Health and Medical Research Council Act (1992)* and the National Statement.

Top End Human Research Ethics Committee

The HREC supports the research activities of the NT Department of Health and Families in its northern zone and Menzies School of Health Research. The HREC also considers applications submitted by non-government health providers located across the 'Top End' of the Northern Territory.

Central Australian Human Research Ethics Committee

The Central Australian Human Research Ethics Committee considers applications for research on humans for all organisations and individuals who wish to conduct such research in Central Australia.

Queensland *(Figure 8)*

In 2006, Queensland Health (QH) established the Mutual Acceptance Model for Multi-Centre Research (MAM4MCR) Project to carry out the dedicated work necessary for advancing QH's agenda to develop and implement a streamlined single review system for multi-centre research within the Queensland public health system, and then with external partners.

The MAM4MCR report of a pilot-evaluation of the QH mutual acceptance model has been tabled and is available on the QH website. The report provides detailed information on the developmental processes which were undertaken by the QH MAM4MCR Project to determine the most effective review model and to identify essential implementation success factors.

A single review model was piloted at seven Human Research Ethics Committee (HREC) sites within Queensland. During the six month pilot-evaluation period, a total of ten multi-centre research protocols entered into the pilot review system. Using a range of investigation methods, feedback on the pilot review system was gathered from the key users. A set of 41 recommendations were tabled.

QH is aiming to implement the mutual acceptance model for multi-centre ethical review in early 2009. The IT platform to support the Queensland model will go live in early October 2008 and be compatible with similar platforms in New South Wales and Victoria.

South Australia

In February 2008, the South Australian Department of Health commissioned an independent review of human health research ethics processes. The objectives of the review were to examine:

- The overall effectiveness, efficiency and capacity of SA human research ethics committee system and to consider how the SA HREC system could be improved.
- The current approaches for managing ethical reviews of multi-centre research in SA, and to consider whether these approaches could be improved in the context of national and international developments, and, if so, how.

The SA Department of Health is currently analyzing the recommendations of the review and facilitated a Statewide Research Ethics Forum in early December 2008.

Tasmania *(Figure 9)*

The University of Tasmania (UTAS) and the Department of Health and Human Services (DHHS) are the major stakeholders in the conduct of research involving humans in Tasmania. On 1 January 2002, a unified Human Research Ethics Committee (Tasmania) Network (the Network) began operating a Statewide structure for the consideration of human research ethics.

The Network is a cooperative arrangement between the DHHS and the UTAS and was set up to provide for an independent system for ethical review of research applications.

The Network made up of two NHMRC registered Human Research Ethics Committees:

- The Tasmania Social Science Human Research Ethics Committee.
- The Tasmania Health and Medical Human Research Ethics Committee.

The third Network committee is the Scientific Research Advisory Committee which considers the scientific validity of research methodology before an application is considered by the Tasmanian Health and Medical Research Ethics Committee.

Victoria *(Figure 10)*

Victoria has developed a model for streamlining multi centre ethical review and will implement the model in 2009 and initially review commercially sponsored clinical trials.

Features of the Victorian model are:

- Institutions participating in the streamlined system will have a documented agreement to accept the opinion from a reviewing HREC, without further ethical review.
- The Coordinating Principal Investigator will submit an ethics application to a central secretariat.
- The central secretariat will triage applications to the next appropriate HREC meeting.
- Reviewing HRECs in the streamlined system will produce a single decision as well as conduct monitoring and reporting functions. Each reviewing HREC will have access to appropriate scientific expertise.
- Host institutions for the proposed research will conduct site specific assessment (SSA) in parallel with streamlined ethics review and provide authorisation (or not) of the SSA.
- Once SSA is authorised at a site the research can commence at that site.
- A Consultative Council will have oversight of the ethical review system.

Western Australia *(Figure 11)*

WA supports the need to streamline processes for ethical and scientific review of multi-centre research projects. The WA approach recognises the value of one HREC undertaking the full ethical and scientific review of a multi-centre project while also acknowledging the role of each approved participant/local HREC in the final decision by a hospital to participate in that research.

The process does not grant automatic ethics approval based on another HREC conducting a full review but has a recognised prior review pathway that allows an expedited ethics review in conjunction with the site specific governance review. This is not a full review and is essentially an ‘accept or reject’ process.

Figure 6: NSW model for multi-centre ethical review

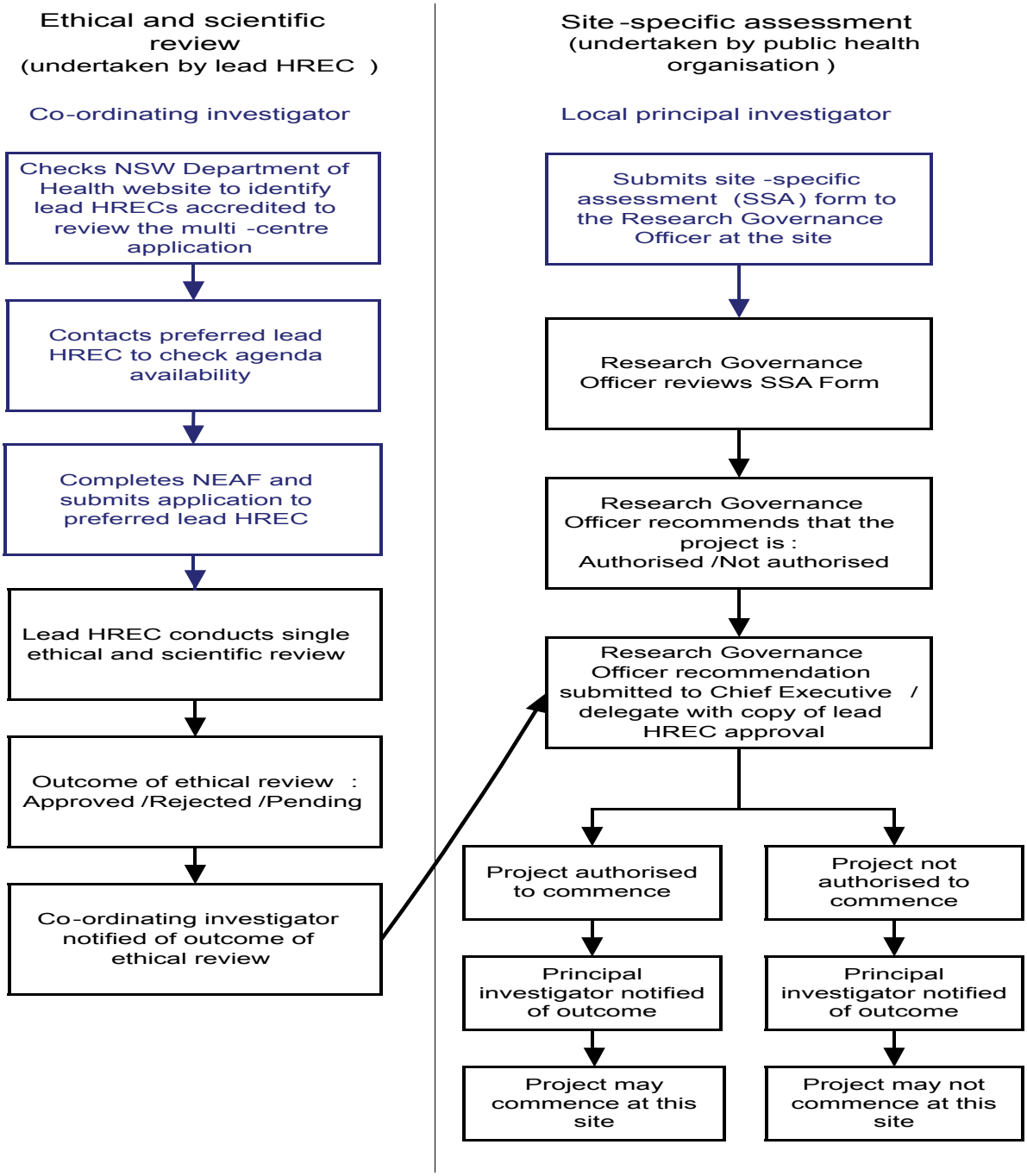
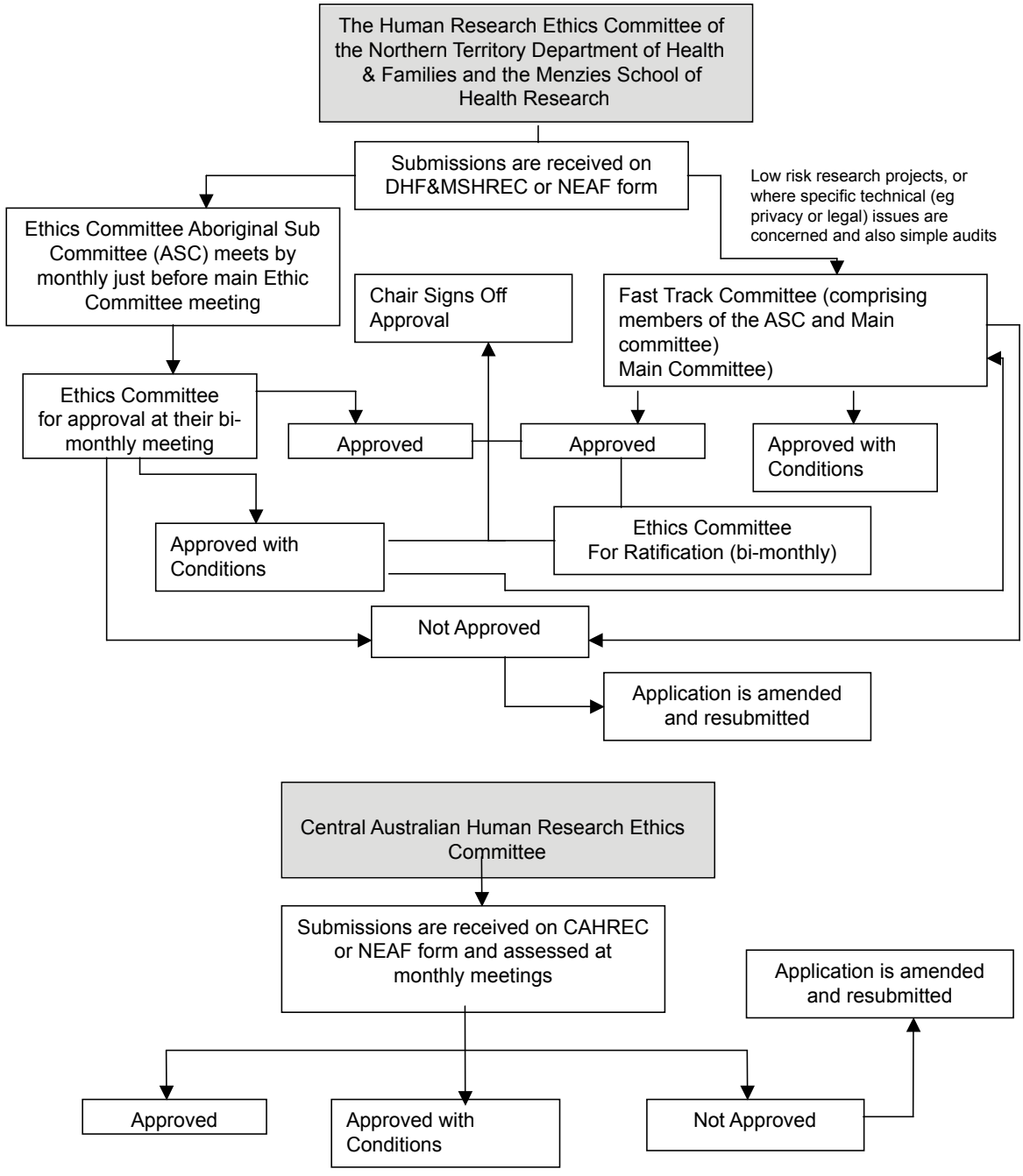


Figure 7: Northern Territory model for multi-centre ethical review



Note: Research Proposals that are Northern Territory wide are required to submit applications to both committees

Figure 8: Queensland model for multi-centre ethical review

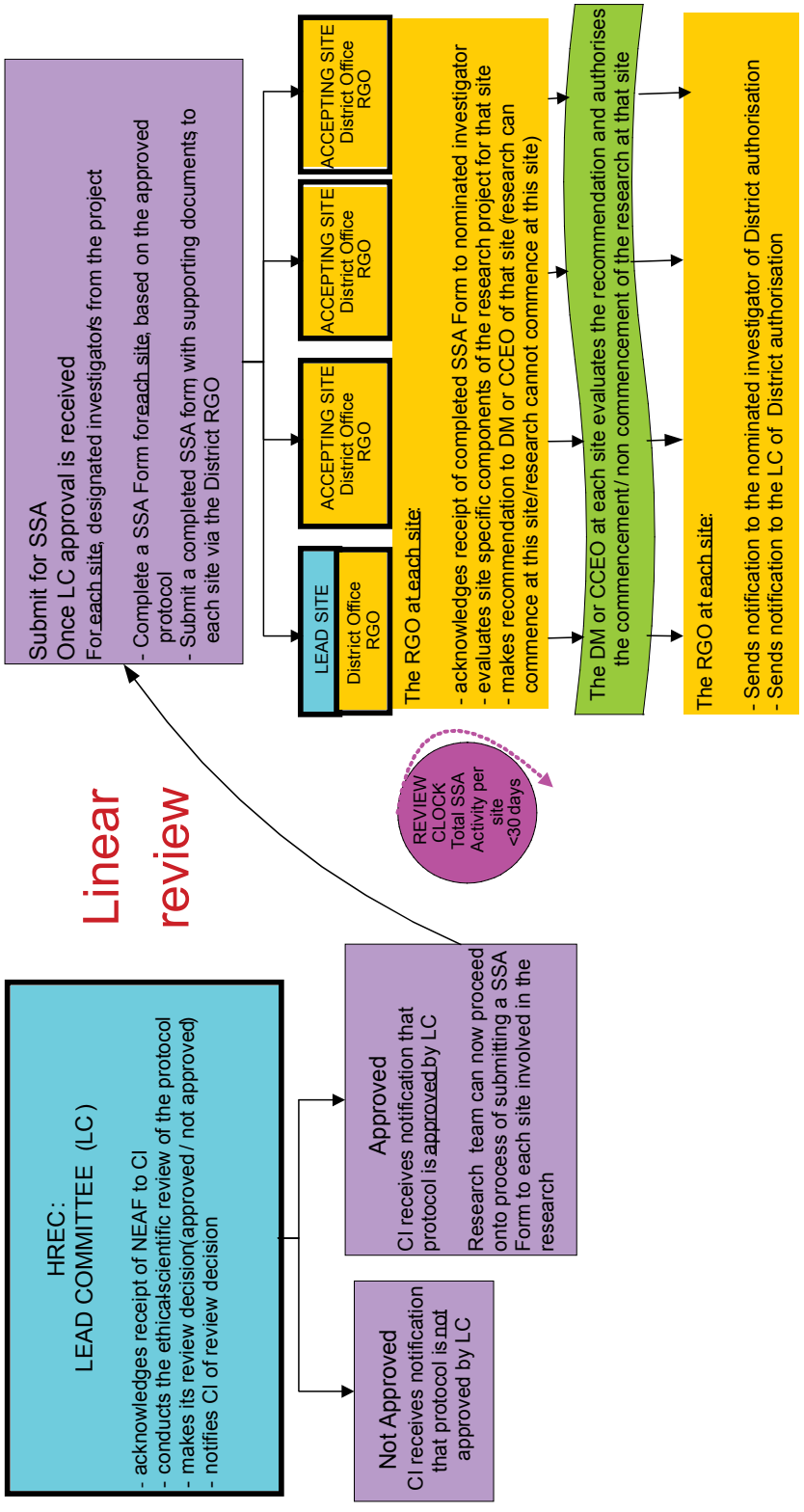
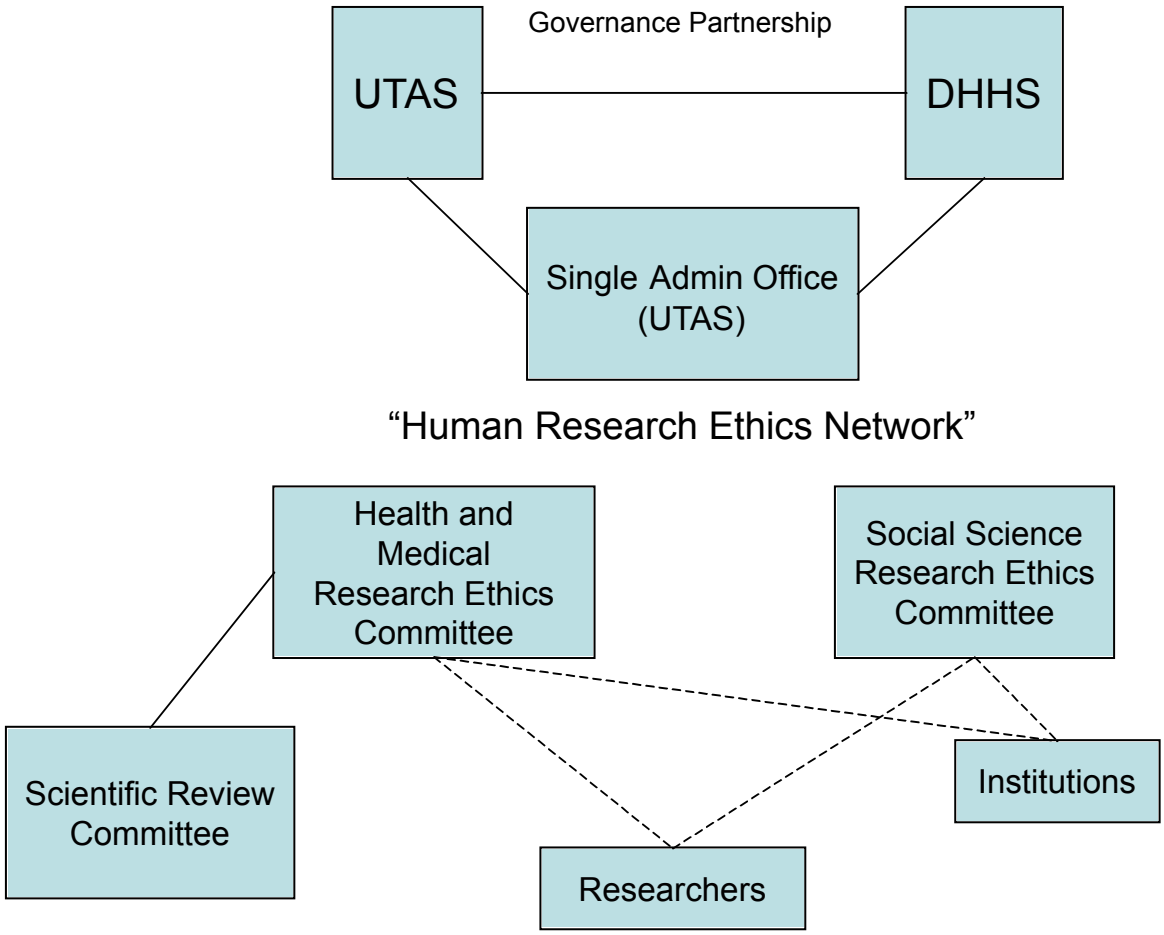


Figure 9: Tasmanian model for multi-centre ethical review



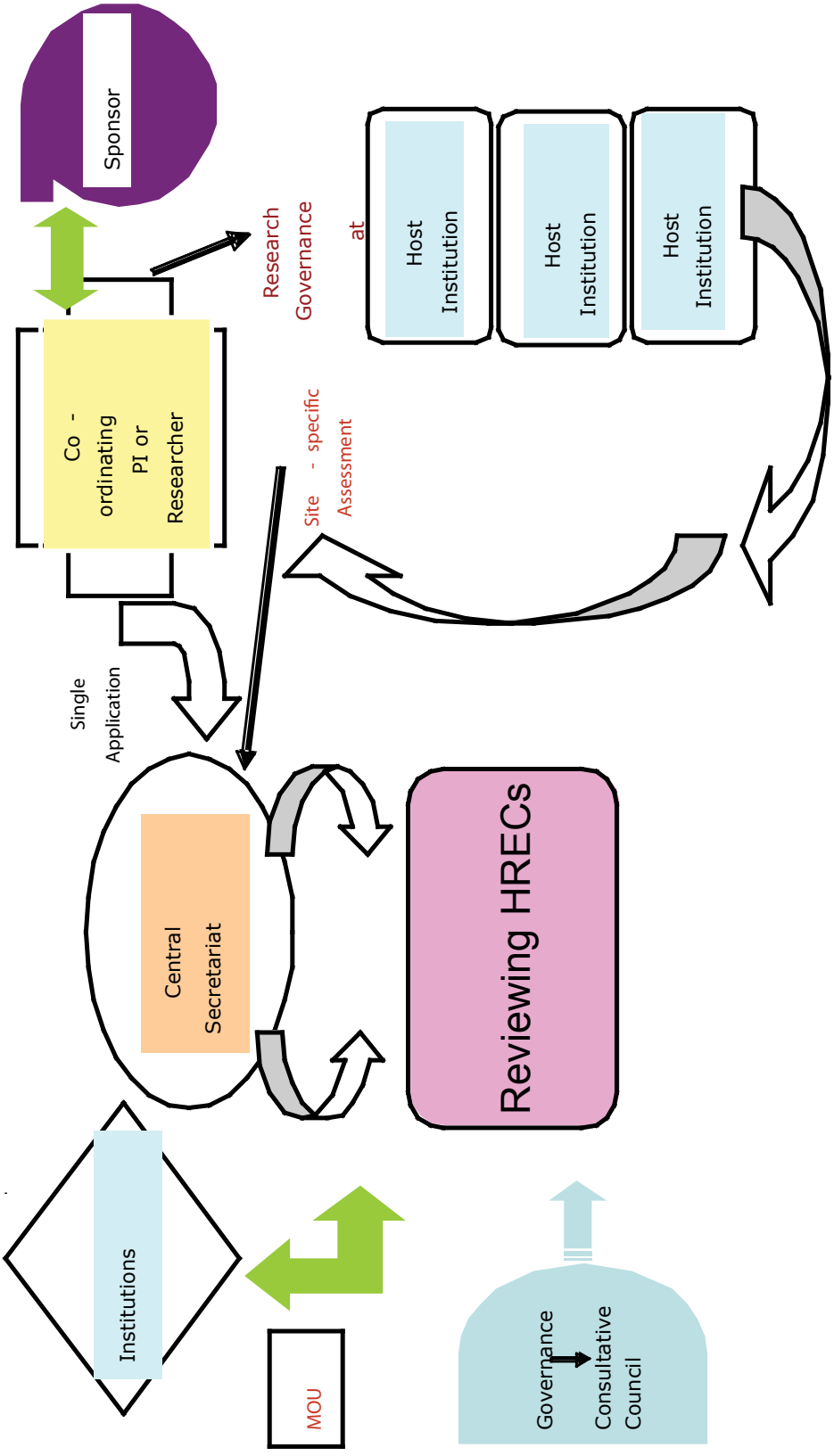


Figure 10: Proposed model for multi-centre ethical review in Victoria

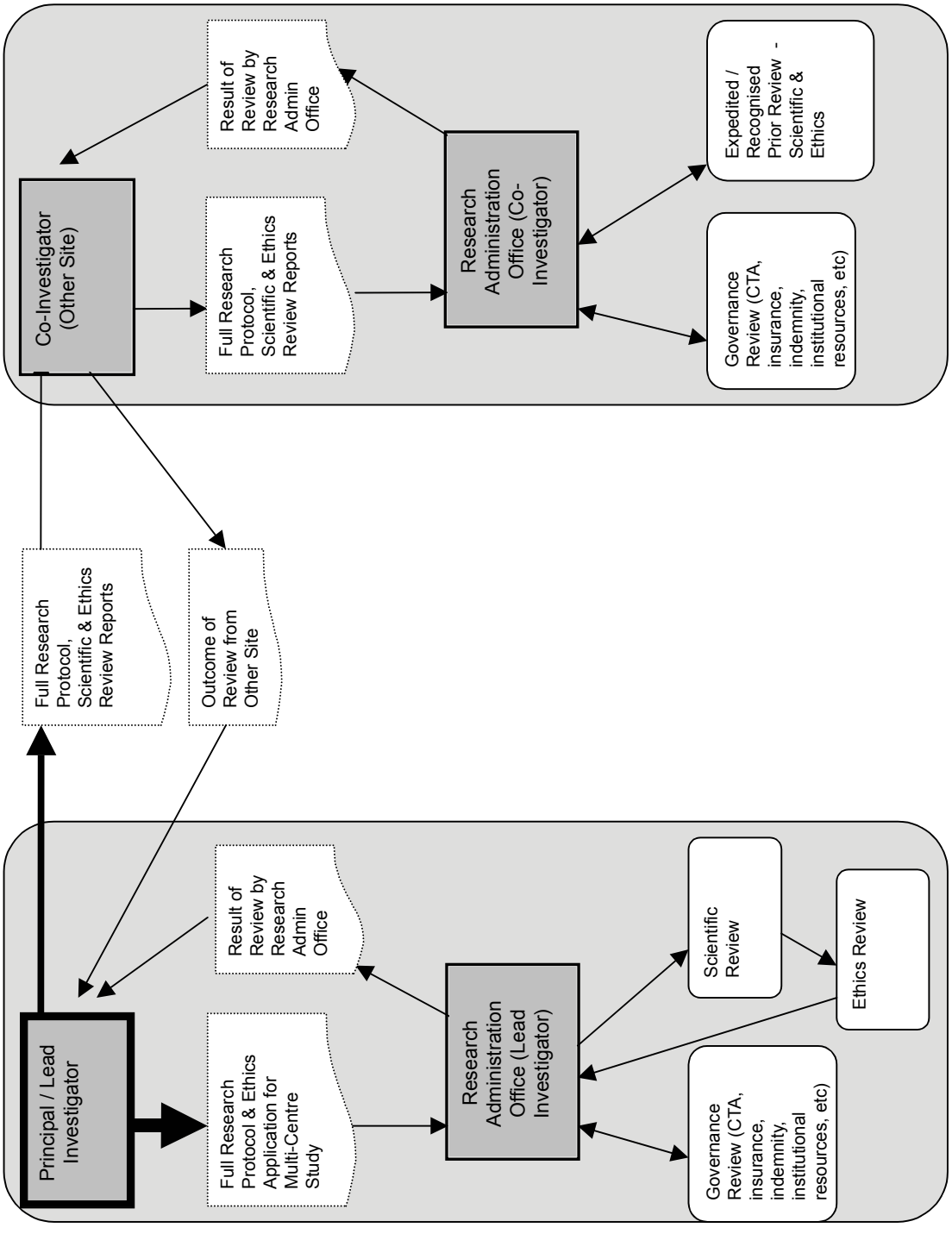


Figure 11: Western Australian model for multi-centre ethical review

Part E

Appendix B Glossary

accreditation	The process by which a HREC is assessed as capable of acting as the single reviewing HREC.
accreditation standard (NSW)	The standard a HREC must meet in order to be accredited as the HREC conducting a single ethical and scientific review.
clinical trial	Human research involving an unapproved or approved therapeutic good, intervention or treatment.
ethical / unethical	Right or morally acceptable / wrong or morally unacceptable.
ethical review	Review of a human research proposal by a HREC or other body.
ethical review body	Body set up to carry out the ethical review of human research. See: HREC.
ethics	The concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.
HREC	Human Research Ethics Committee. An institutional ethics committee constituted according to the National Statement on Ethical Conduct in Human Research. Its primary purpose is to protect the rights and welfare of participants in research. Its secondary purpose is to facilitate human research that will benefit the community.
indemnity	An agreement whereby one party agrees to protect another against anticipated loss or damage.
jurisdiction	An Australian State or Territory.
low risk (research)	Research in which the only foreseeable impact of the research participant is discomfort.
monitoring (of research)	The process of verifying that the conduct of research conforms with an agreed standard. In the proposed national system, the primary monitoring is on the ethical conduct of research.
multi-centre research	A research project undertaken by a group of institutions at one or more one sites.
multi-site research	A research project undertaken by a single institution at more than one location.
principal HoMER researcher	The researcher within a group of researchers who will be the principal contact of the reviewing HREC in relation to a multi-centre research proposal.
principal investigator	Person nominated to take responsibility within the team of researchers for the reporting of research progress at a particular site.

protocol	A document that provides the background, rationale and objectives of the proposed research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.
research	Investigation undertaken to gain knowledge and understanding.
research governance	A framework through which research is effectively administered and oversighted, so that it meets appropriate standards of quality, safety, privacy, risk and financial management.
reviewing HREC	An HREC accredited by the HoMER enabling system that conducts a single ethical and scientific review of multi-centre research projects. Lead HRECs are responsible for overseeing the research project at all sites.
risk	The magnitude and probability that an event will occur.
scientific review	A review of proposed research to consider the level of scientific validity of research methodology before the proposal is considered by a Human Research Ethics Committee.
serious adverse event (SAE)	Any untoward medical event that: • results in death • is life-threatening (NOTE: The term "life-threatening" refers to an event/reaction in which the patient was at risk of death at the time of the event/reaction; it does not refer to an event/reaction which hypothetically might have caused death if it were more severe) • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity. Refers to clinical trials.
serious unexpected suspected adverse reaction (SUSAR)	A serious adverse event for which there is some degree of probability that the event is an adverse reaction to the administered drug and the adverse reaction is unexpected.
single ethical and scientific review	The ethical and scientific review of an accredited HREC that will be accepted by all institutions participating in a specific multi-centre research project.
single site	A research project undertaken at a single location.

Part E

Appendix C Key Information Sources

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