Final Report
Review and Evaluation of the National Certification Scheme for Institutional Ethical Review Processes

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1 Glossary

1.1 Acronyms

Acronym	Description
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
LHD	Local Health District
MoU	Memorandum of Understanding
NCS	*National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-Centre Research*
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance scheme of ethical and scientific review of clinical trials
PHO	Public Health Organisation – e.g. public hospitals

1.1.1 Definitions

Term	Definition
Certified Institution HREC	The HREC of an institution whose ethics review processes have been certified under the NHMRC National Certification Scheme.
Ethics Review	In this report, the term ethics review is inclusive of the process of scientific review.
Institution	Includes the decision-making agent with responsibility and accountability as the head of an institution, e.g. Chief Executive Officer, Vice-Chancellor, Chief Executive or their delegate determined by the governance arrangements of the institution[1].
Jurisdiction	An Australian State or Territory and their lead agencies involved in human research, usually a Department of Health.
Lead HREC (NSW Definition)	A local HREC accredited by the Director-General of the NSW Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research and/or (b) general research[2].

[1] Institution as defined in Certification documentation https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/how-apply-certification.
[2] Operation manual, HREC Executive Officers http://www.health.nsw.gov.au/ethics/Documents/GL2010-014.pdf.

2 Executive Summary

This report summarises the findings from the *Review and Evaluation of the National Certification Scheme for Institutional Ethical Review processes* (NCS). The review was undertaken between April and November 2016 by Think Different Consulting Pty Ltd on behalf of the National Health and Medical Research Council (NHMRC). The review sought views on evaluation questions from targeted stakeholders via semi-structured interviews and an online survey. Stakeholders were asked about the benefits and value of the NCS, their experience of implementing the NCS (for institutions) and how they thought the NCS might be improved in the future.

The feedback in some areas varied widely between stakeholder groups and it was not always possible to determine a prevailing view or clear path forward on some questions or ideas. While all of the feedback is summarised in the body of the report, the findings and future options focus on the areas where clear agreement was evident.

The first section of the report focused on stakeholder experiences of the value of and implementation of the current NCS**.** The findings here were generally consistent and the key findings are summarised as follows:

- The most frequently reported benefit of the NCS was the improved trust between certified institutions.
- The process of preparing for certification was valuable and improved ethics review processes and efficiency, although the scale of improvement varied. The certification process was seen by institutions as valuable and an opportunity for internal review of processes.
- Feedback from institutions on the certification process was overwhelmingly positive. NHMRC staff were consistently singled out for their helpful and responsive approach to queries.
- The site assessment was the most positive aspect of the NCS.
- No institution reported any substantive changes to the deliberative process used by the HREC to review applications.
- The renewal of certification processes was not viewed positively, with long delays in feedback and communication from the NHMRC consistently reported.
- Institutions were unclear on how the renewal process was able to determine ongoing compliance or identify if processes had “slipped”.
- The tools available on the Human Research Ethics Portal (HREP) were poorly utilised by stakeholders.
- The cost impact of implementation of the NCS was primarily a time cost borne by the professional staff during initial certification and related to ongoing monitoring, submission of annual reports and renewal of certification. There was no reported additional workload to HREC members other than the Chair.
- The time invested in preparing for and undergoing certification was considered by all institutions to be time well spent.
- The NCS, the certification process, and any benefits that derive from being a certified institution are not well understood outside of certified institutions.
- Consultation responses showed little understanding of the current NCS scope and focused on future direction.
- Consistency in ethics review was considered by stakeholders to be part of the scope of the current NCS.

The second section of the report captured stakeholder feedback on the future direction of the NCS. This included the potential for changes in scope, certification criteria and categories and the process of certification itself.

The key findings on the future direction on the NCS are:

- That the NCS should continue.
- NHMRC should continue to operate the NCS, though opinions differed on whether an expert review panel would add value to the existing assessment process.

- Many stakeholders supported amendment to the scope of the NCS to include consideration of the HREC deliberative process, consistency of process between institutions and the requirement to use standard documentation to support processes as a condition of certification.
- The majority of stakeholders believe that the current categories of certification are useful and appropriate. Jurisdictions and research managers were more likely to recommend amendment to the available categories

Options for improvement of the NCS

- Establishment of a clear and transparent certification cycle. This cycle should clearly state the length of the initial certification period, how long certification can be renewed for and how often the full certification process, including site visit, takes place. Based on current literature, a five-year certification cycle may be reasonable with an interim review/renewal at 3 years. Any agreed timeframe would be dependent on available NHMRC resources.
- Introduction of additional ethically distinct categories of research as required such as research involving young people, early phase clinical trials and data linkage.
- Removal of the option to be certified in "other" or non-specific categories.
- Expansion of the scope of the NCS to review and certify all research ethics review processes of an institution, including the review processes of low and negligible risk research in order to ensure consistency between certified institutions.
- Provision of a suite of standard forms associated with post-approval and monitoring processes.
- Introduction of attendance at a HREC meeting as part of the on-site certification assessment.
- Provision of a "best practice" standard operating procedures template for certified HRECs.
- Amendment of the certification criteria to ensure that terms of reference and standard operating procedures (including any specified timeframes) are publically available.
- Development of a communication strategy to improve ongoing engagement of certified institutions with available tools and resources.
- Continuation of the annual meeting of certified institution HREC Chairs and Executive officers.
- Reintroduction of the previously established panel of expert assessors which could be used to supplement NHMRC's expertise available for site visits.
- Introduction of a requirement that certified institutions must accept the review of other certified institutions.

3 Introduction

Think Different Consulting was engaged by NHMRC in April 2016 to undertake a review and evaluation of the National Certification Scheme. Throughout this report, the National Certification Scheme is referred to as the NCS.

The purpose of this report is to present the evaluation findings and discuss options for the future of the NCS. The report also addresses a secondary objective of identifying other ethical review process assurance frameworks used in Australia, and providing advice on what elements or functions could be of benefit to the NCS.

The data used in this report was gathered through stakeholder telephone interviews and an online survey.

3.1 Background

The Harmonisation of Multi-Centre Ethical Review (HoMER) initiative was developed to support a national, harmonised approach to single ethical review. The outcome of the HoMER initiative is the National Approach to Single Ethical Review of Multicentre Research (National Approach). The NCS was one of a number of tools that were developed to support the National Approach.

Certification provides an assurance to stakeholders that the policies, processes and procedures of an

institution and its HREC comply with an agreed set of national criteria for the conduct of ethics review of multi-centre human research. The NCS was developed to build trust between institutions by providing an assurance to third parties that an institution's ethics review processes conformed to an agreed national standard. The NCS is voluntary and is in addition to the registration and reporting requirements of all HRECs.

The NCS is specifically designed to respect institutional autonomy with respect to its decision regarding whether research should be conducted at a given site. The current certification criteria and practices exclude matters of project governance or site assessment. Advice received from a certified institution's HREC that is accepted by another institution does not replace the need for local review of governance matters.

Separate to the NCS, in 2013, a number of jurisdictions introduced the National Mutual Acceptance (NMA) scheme. The NMA scheme was established via an agreement between Victoria, NSW and Queensland and replaced the pre-existing interstate mutual acceptance scheme (IMA). This Memorandum of Understanding (MoU) enabled cross-jurisdictional acceptance of ethics review of clinical trials taking place in public health organisations (PHO) within jurisdictions that had signed the MoU. South Australia joined the NMA scheme in 2015 and the ACT joined in 2016. In December 2015, the parties to the MoU extended the scope of NMA to include all multi-centre human research taking place in PHOs. The NCS remains a critical tool in the success of the National Approach and certified status is a necessary (but not sufficient) pre-requisite for institutions to participate in the NMA scheme.

Prior to the National Approach and the NMA scheme, certification or accreditation schemes had emerged in parallel across the eastern seaboard states, sometimes in combination with the use of a central allocation system for the assignment of research proposals to HRECs. Victoria and NSW developed accreditation schemes for 'Lead' HRECs as part of State based policies of single ethical review. Those policies emerged from their respective Departments of Health and applied to public health organisations. As NMA developed, the Eastern states agreed that the NHMRC NCS Criteria would form the certification standard. Queensland adopted the NCS as the local standard from the outset and changes were required to jurisdictional requirements in NSW and Victoria.

In order for ethics reviews of human research to be accepted under NMA, the institution conducting the review must be certified under the NHMRC NSC and also be an accredited Certified Reviewing HREC under the NMA scheme. The National Approach differs from NMA in that it is open to all sectors – universities, as well as public, private and Catholic hospitals, rather than being limited to public health organisations. The National Approach encourages all institutions (regardless of sector) to accept the review of certified institutions and is agnostic as to institutional or jurisdictional information management systems. It does not require the signing of formal or informal agreements (e.g. MoUs) between participating institutions.

The NMA MoU imposes additional requirements at a jurisdictional level around the type of institution that is able to participate and minimum data collection requirements at a system level. Under the MoU, only PHOs can participate in the NMA scheme. In addition, only jurisdictions that use an information management system developed by a private provider, Infonetica, can participate in the NMA scheme. As these policies and systems are managed through health departments, universities and other private health or non-health organisations are therefore considered outside the scope of NMA; although a university or non-PHO institution can still accept an ethics review conducted by a NMA participating institution. However, the restrictions of the NMA have, in practice, prevented non-NMA participating institutions from accepting an ethics review from an NMA-participating institution.

3.2 Project Scope

The project followed the parameters outlined in the Approach to Market, *Review and Evaluation of the National Certification Scheme for Institutional Ethical Review Processes* – ATM 16/009.

The project scope included:

- evaluating the efficacy of the NSC as a means of improving the quality of institutional ethical review processes and in recognising established high quality processes
- identifying the strengths and weaknesses of the current NCS
- identifying benefits to the research sector of maintaining the NCS
- providing options and recommendations for improving the NCS.

The scope of this project and this report is limited to the review and evaluation of the NCS. The review and report does not evaluate any aspect of the NMA scheme, the National Approach or other initiatives related to the multicentre ethics review of research proposals. Revision of the *Certification Handbook National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research*, November 2012, other related documents or the Human Research Ethics Portal are also out of scope for this project.[3]

3.3 Consultation Methodology

The purpose of the consultation was to canvas a diverse range of views from stakeholders that had experience of the NCS. However, the methodology was weighted towards seeking feedback from certified institutions and their HRECs. Views of sponsors and researchers as end users were actively sought to ensure a balance between process considerations of institutions and jurisdictions and the outcomes of the review process from the perspective of researchers and sponsors.

A combination of telephone interviews and survey responses were used to collect data. Interviews provided an in-depth exploration of particular topics and were semi-structured to allow for discussion on the operational aspects that may impact the operation of the NCS. They were used as a platform to test concepts that emerged from the desktop review of international models and alternative schemes. Raw data was collected and analysed for relevance.

As the timeframe for consultation was limited, an online consultation option was provided to capture feedback from stakeholders that were not identified for a telephone interview. This two-part approach promoted a wide cross section of feedback across the sector. The survey was developed when the interviews were well advanced to have the opportunity to test ideas that emerged from the interviews.

3.3.1 Semi-Structured Interviews

At the initiation meeting held on the 28th April 2016, NHMRC identified the following key stakeholder groups as critical to the consultation process:

- HREC chairs, members and support staff
- clinical trial sponsors and researchers with experience using the NCS
- staff at the jurisdictional agencies responsible for the management of health research at the state level.

The list below outlines the institutions, organisations, agencies and individuals that were invited to participate in the semi-structured telephone interviews. These stakeholders were selected based on achieving a balance of perspectives across Australia: certified and non-certified institutions and jurisdictions involved in the NMA scheme, as well as those that have chosen not to be involved in the NMA scheme. NHMRC staff attended a half-day workshop and provided information on the NCS from the perspective of scheme administrators and assessment panel members.

Jurisdictional officers were interviewed to develop an understanding of the intersection between the NCS and State-based certification or accreditation schemes. As some jurisdictional schemes pre-dated the

[3] On 11 November 2016, NHMRC decommissioned the Human Research Ethics Portal (HREP) and centralised documentation relevant to the NCS and National Approach on the NHMRC website. Materials related to the NCS can now be found at: https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review-multi-centre-research.

NCS, the interview was also used to explore success factors and opportunities for improvement from the system management perspective.

Targeted Consultation Interviews – Stakeholder List

	Organisation	State
HRECS		
1.1	ACT Health	ACT
1.2	Royal Adelaide Hospital	SA
1.3	Bellberry Pty Ltd	SA
1.4	St John of God Healthcare	WA
1.5	St Charles Gairdner Group	WA
1.6	University of Tasmania	TAS
1.7	Cabrini Hospital	VIC
1.8	The Royal Children's Hospital, Melbourne	VIC
1.9	Hunter New England Local Health District	NSW
1.10	Cancer Institute NSW Population and Health Services Research	NSW
1.11	The University of NSW	NSW
1.12	Charles Sturt University	NSW
1.13	University of Queensland	QLD
1.14	Darling Downs Hospital and Health Service	QLD
1.15	Menzies School of Health Research	NT
1.16	Mater Health Service	QLD
Research Managers and Directors		
2.1	St Vincent's Hospital, Melbourne	VIC
2.2	Melbourne Health	VIC
2.3	Northern Sydney Local Health District	NSW
2.4	Metro South Health	QLD
2.5	University of Western Australia	WA
State Agencies - NMA		
3.1	Queensland Health	QLD
3.2	SA Health	SA
3.3	Victorian Department of Health and Human Services	VIC
3.4	NSW Ministry of Health	NSW
State Agencies – Non-NMA		
3.5	WA Health	WA
Sponsors		
4.1	St Jude Medical	-
4.2	Janssen (Medical Devices)	-
4.3	Novartis	-
4.4	Parexel	-
4.5	Merck Serono	-
4.6	INC Research	-
4.7	Q-Pharm	-
Researchers		
	Invitations to participate were circulated to researchers through national and university researcher and clinician networks.	

Interviews used guiding questions to elicit feedback on questions, including:

- experiences of the operation of the NCS
- demonstrated or perceived value of the NCS to the stakeholder/their organisation/ jurisdiction
- if appropriate, interaction with jurisdictional systems and processes
- how related documents and the HREP are used
- benefits to the sector of maintaining the NCS
- operational effectiveness and options for improving the efficacy or quality of the NCS

- categories of certification, suitability of current categories, how and by whom categories should be determined or amended.

The full list of interview questions is at appendix 9.1.

3.4 Online Consultation Response (NCS Survey)

The questions for the survey were developed based on early feedback from the structured interviews. In addition to the above questions on the functioning of the NCS, the survey also tested views on beneficial changes that could be introduced. The survey was intended for broad distribution with an invitation to participate circulated by the NHMRC to selected stakeholders. The survey was also promoted in the NHMRC's *Research Tracker* and *Health Tracker*.

3.4 Summary – Consultation Response Data

Requests for consultation interviews were well received with the majority of invitations accepted. Some teleconference interviews were conducted with one person at a time, however the majority took place with a group of senior representatives from the HREC and the organisation.

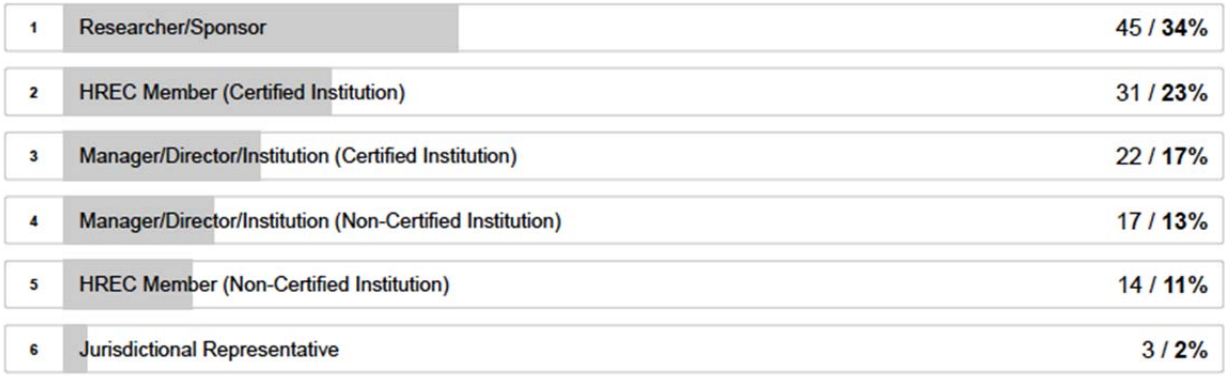
Targeted Interview Requests Vs Response Rate

Stakeholder	Approached	Interviewed	No Response/Unavailable
HREC	**17**	**13 (10 certified, 3 non-certified)**	**4**
Research Managers/Directors	**5**	**4 (3 certified, 1 non-certified)**	**1**
Jurisdictions	**4**	**4 (3 NMA, 1 non-NMA)**	
Sponsors/Researchers	**7**	**6**	**1**
NHMRC Panel Members	**2**	**2**	

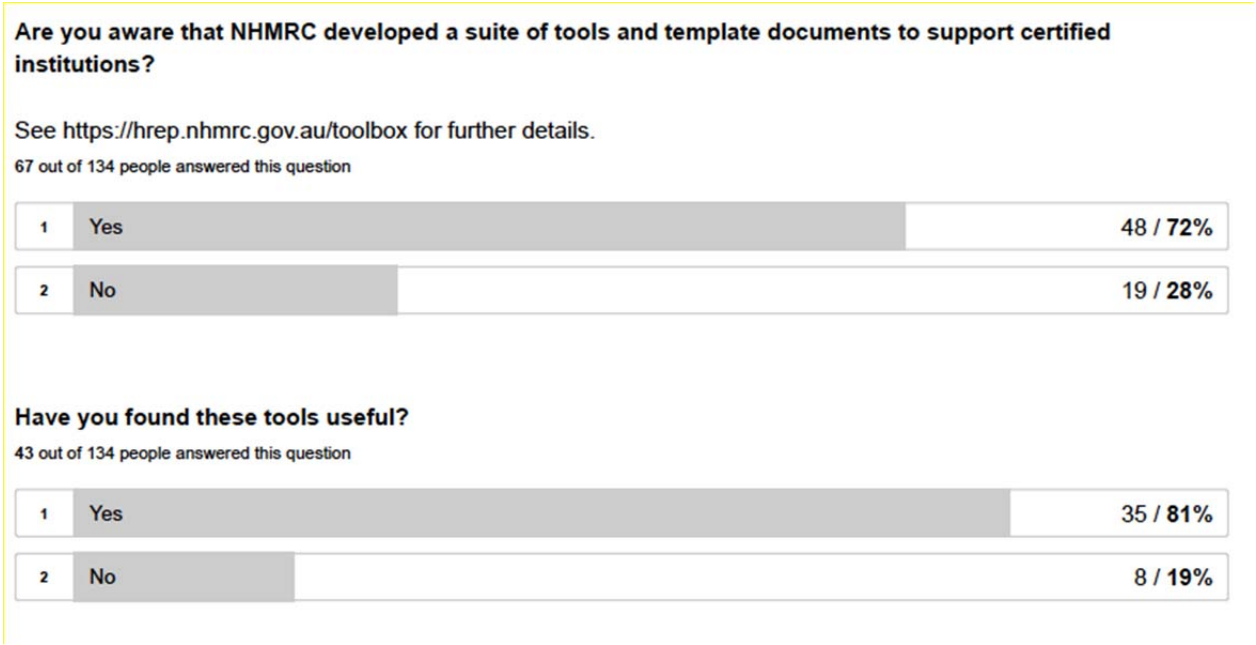
NCS Survey Responses

A total of 134 responses to the survey were received with the majority of responses from sponsors or researchers (34%). All respondents were asked to nominate a single identifying category in their response to this question:

Q. You are answering this question as a:



Answers to the survey questions were not compulsory and some questions had very low response rates. Examples were:



Due to the low response rate for particular questions, the discussion of the findings is not equally weighted. This is congruent with the telephone interview responses.

The full details of the survey can be found in the general report in appendix 9.2.

3.5 Limitations of the Methodology and Report

Stakeholders' availability and engagement: The identification of stakeholders for the semi-structured interviews aimed to cover a wide range of perspectives. Efforts were made to allow for a balance of stakeholder views between States and Territories, institutional size, and inclusion of non-certified institutions. However, some underrepresentation may have occurred as the views of stakeholders who were less engaged in the NCS are underrepresented in the sample.

Limitations of the survey: The online consultation tool was circulated widely and responses were collected anonymously. The online consultation responses lacked the clarity of the telephone interviews. In addition, the quality and utility of the responses were more variable than data collected from the semi-structured interviews. The survey provided an opportunity for respondents to provide free text comments. This was used by some respondents to comment on other aspects of ethics or governance which they felt needed to be addressed. While all comments were reviewed, comments on topics that were considered to be out of scope (e.g. relating to research governance) were not included in the analysis.

Duplication of stakeholder input: As the survey was anonymous, it was not possible to tell if individuals participated in both the telephone interview and the survey. At least one individual submitted two responses to the online survey. This was based on that individual having previous experience as an assessor prior to their current role as an ethics officer for a non-certified institution and was only done after notifying NHMRC of their intention to submit two responses.

4 International Approaches to quality assurance mechanisms for Human Research Ethics Committees

4.1 Literature Review

A literature review was conducted in order to compare different models of assurance of ethics committees. The term 'accreditation' is used in this section as the majority of international models are accreditation models. The International Standards Organisation (ISO) defines the difference between 'accreditation' and 'certification' as:

> ***Accreditation***
>
> *The ISO defines accreditation as a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.*
>
> *Accreditation entails the endorsement of a conformity assessment body's competence, credibility, independence and integrity in carrying out its conformity assessment activities. This enhances the authority of conformity assessment bodies in conducting its conformity assessment activities in certification and inspection.*
>
> ***Certification***
>
> *Certifications are sought from conformity assessment bodies to demonstrate the applicant's compliance with specified standards and defined by the ISO as a third-party attestation related to products, processes, systems or persons.*
>
> *In essence, certifications are third-party endorsements of an organisation's systems or products, while accreditation is a third-party endorsement of the certification*[4]*.*

Both accreditation and certification schemes involve assurance of minimum processes or system standards, however accreditation systems involve additional assurance standards of the certifying body. Most notably, the UK has pursued the path of obtaining accreditation for its Health Research Authority (HRA) against ISO standards for quality management. This involves considerable ongoing investment in the quality processes that support the accreditation of ethics committees at the system (State equivalent) level.

The review explored the potential application of international mechanisms to the Australian context as a means of augmenting the current NCS framework. The majority of literature was based on small-scale pilots, websites of other assurance schemes from other countries or were summary articles on how other jurisdictions were approaching assurance approaches.

The review was conducted using Google and a number of online journal platforms such as Ovid and ProQuest. Initially the timeframe was restricted to the past ten years and used broad terms such as "ethics review committee" and "research" or "human" in combination with words such as "accreditation", "certification".

The *International Compilation of Human Research Standards* (2016 Edition)[5] and the SATORI Anne 3 Paper – *Ethical Assessment in Different Types of Organisations*[6] were used to identify the appropriate countries and bodies that have developed standards for certification and/or accreditation of the ethical review process. The literature in the area of quality standard of research ethics committees is limited and the review presents the best available information.

[4] https://www.isoqsltd.com/about-us/iso-accredited-certification/; http://www.qualitymag.com/articles/85483-what-s-in-a-name-accreditation-vs-certification accessed 23 October 16.
[5] http://www.hhs.gov/ohrp/international/compilation-human-research-standards/ accessed on 29 July, 2016
[6] SATORI Project http://satoriproject.eu/work_packages/comparative-analysis-of-ethics-assessment-practices/ accessed 29 July 2016.

4.2 International Approaches to Accreditation and Certification

4.2.1 United States

The United States (US) Institutional Review Boards (IRBs) perform a similar role to HRECs. IRB decisions are governed by the Federal Policy for the Protection of Human Subjects, or the 'Common Rule'. The Common Rule is organised into separate regulations by 15 Federal departments and agencies, the Common Rule outlines the basic provisions, informed consent and Assurances of Compliance required by each department or agency. The policy also makes provisions for institutions to enter into joint review or similar arrangements, with the approval of the department or agency head, for the purpose of "avoiding duplication of effort."[7]

Notice of Proposed Rulemaking

In the US the current climate with regards to review of multi-centre research is set to change. In September 2015 a Notice of Proposed Rulemaking[8] was published. The revisions in the proposal as a whole intend to "modernize, strengthen, and make more effective" the Federal Policy for the Protection of Human Subjects. The revision regarding the current rule on cooperative research outlines a mandate on all U.S. institutions, and requires that a multicentre study rely upon the review of a single IRB, with exceptions depending on the type of study being reviewed. This will be coupled with an extension of the Common Rule and its regulations to cover unaffiliated IRBs, thereby offering federal wide assurance and appeasing many of the concerns raised in public comment and discussion[9]. For ease, the need for department or agency head approval will also be removed. This effectively creates an environment of "single ethical review" that is enabled through ties to funding from federal agencies. This differs from the Australian context where there is no linkage between federal research grant funding (or eligibility to receive funding) and a requirement to accept approval by a certified HREC (or single HREC).

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)

AAHRPP is an independent organisation that uses a peer review approach to accredit human research protection programs internationally. Internationally over 220 organisations have accreditation from the AAHRPP.[10] Their goal is to recognise and accredit high quality human research protection programs to promote excellence and ethically sound research. Effective, efficient and innovative practice is encouraged. The standards are US based and focus on the US regulatory requirements, the common rule and Good Clinical Practice (ICH GCP).

The accreditation criteria address three domains:

1. the organisation or institution
2. the Institutional Review Board or Ethics Committee
3. researcher and research staff.

The AAHRPP assessment process comprises of four sequential steps. The end-to-end assessment process can take between 12-18 months[11].

[7] Protection of Human Subjects, 45 C.F.R. § 46.114 (2009).
[8] Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53931 (Sep. 8, 2015) (to be codefied at pt. 10 CFR 745, pt. 14 CFR 1230, pt. 15 CFR 27, pt. 20 CFR 431, pt. 22 CFR 225, pt. 28 CFR 46, pt. 29 CFR 21, pt. 32 CFR 219, pt. 34 CFR 97, pt. 38 CFR 16, pt. 40 CFR 26, pts. 45 CFR 46 & 690, pt. 49 CFR 11, pt. 6 CFR 46 & pt. 7 CFR 1).
[9] Discussion can be found on page 53981 of the above, and is summarised on the Office for Human Research Protections website, http://www.hhs.gov/ohrp/regulations-and-policy/regulations/nprm-2015-summary/index.html accessed 28 July, 2016.
[10] http://www.aahrpp.org/learn/find-an-accredited-organization accessed 29 September 2016.
[11] https://admin.share.aahrpp.org/Website%20Documents/2015%20Evaluation_Instrument_for_Accreditation%28v2%29.pdf accessed 29 September 2016.

The process for assessment of an institution is as follows:

Step 1 – Self-Assessment and internal review by institution/organisation

Step 2 – Application from the organisation

Step 2 – Site visit, includes review of step 2 documentation

Step 4 – Report of site visit, follow up and decision on accreditation status by the governing council.

Key aspects of accreditation under the AAHRPP scheme relevant to the NCS:

- Institutions are accredited for an initial three-year period, thereafter the accreditation period is five years. Site visits are conducted every five years.
- AAHRPP provides draft site visit reports within 30 days.
- There is a condition of accreditation that the institution must notify AAHRPP of major changes in membership, structure, ownership or leadership. This requirement forms part of the ongoing monitoring and accountability framework.
- AAHRPP has a clear conflicts of interest policy in place for AAHRPP representatives and reviewers. This transparent approach to managing conflicts would be valuable for any expert panels.
- There are three categories of accreditation, "full accreditation" (meets all standards), "qualified accreditation" (meets most standards but requires corrective action on minor and administrative matters), and "pending accreditation" (awaiting a decision or where criteria are not met). With a "pending accreditation", the organisation must submit an improvement plan, which can give an additional seven months to meet the criteria. Full accreditation may be awarded on resolution of minor matters. If adopted in the NCS, these categories may be useful for communicating to an institution where it is up to in the certification process.
- "Accreditation withheld" status is documented where the organisation does not meet the standards and does not demonstrate commitment to corrective action in a reasonable period. The organisation may reapply at its own discretion with evidence of corrective action.
- There is an appeals process applicable to any decision to withhold or revoke accreditation.
- Annual reports are required from accredited organisations which is largely consistent with what the NCS currently requires. The annual reporting process for AAHRPP includes reporting on:
    - organisational changes
    - resourcing changes
    - changes in program scope
    - catastrophic events.
- Institutions pay a one-time application fee and annual fees thereafter that are based on the number of applications reviewed by the IRB. Where the IRB reviews between 1- 100 studies the initial accreditation fee is USD12,500, for between 101 and 500 studies the initial fee is USD18,800. The yearly fees to AAHRPP for IRBs is USD6,000 p/a for reviewing 1-100 studies a year and USD8,200 p/a for 101-500 studies per year.

The AAHRPP publishes metrics on the performance of accredited institutions each year[12]. Metrics include: type of research; sponsors of research; compensation of IRB members; number of active studies, review timeframes, use of technology and resourcing of professional staff based on the number of studies reviewed.

[12] https://admin.share.aahrpp.org/Website%20Documents/Hospitals-%20Final%20Draft%20(6-21-2016).pdf accessed 29 September 2016.

The assessment criteria are largely assessed based on documentary evidence. However, detailed advice on how to meet the assessment criteria and examples of what information may need to be provided is available in a summary document[13]. Meeting the criteria is arguably only a measure of documentary evidence rather than evidence of what the IRB or its researchers do in practice. The assessment framework primarily assesses process in a similar manner to the NCS (although it is a more complex process). However, a valuable addition to the criteria is the requirement for documented institutional evaluation processes for the ongoing improvement of systems, processes and performance of the IRB. This approach embeds internal review into the accreditation process. One example of this is:

> Element I.5.B. The organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program.[14]

The criteria also outline outcomes for each criterion. For example, the outcomes for element 1.5.B are listed as:

Outcomes

The organization:

- identifies targets for quality, efficiency, and effectiveness of the HRPP
- plans improvements based on measures of quality, efficiency, and effectiveness
- implements planned improvements
- monitors and measures the effectiveness of improvements.

The inclusion of outcomes provides assessment measures for internal and external reviewers.

Another example of outcomes includes the escalation of complaints and concerns. Each of these can be tested through surveys or interviews with researchers and research staff to measure how well embedded a policy is in an organisation, not just its documented existence.

> Element I.5.C. The organization has and follows written policies and procedures so that researchers and research staff may bring forward to the organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process.

Outcomes

- researchers and research staff know how to obtain answers to questions regarding the HRPP
- researchers and research staff know how to express concerns or convey suggestions about the HRPP
- researchers and research staff find the organization responsive to their questions, concerns, and suggestions.

Certified IRB Professional (CIP®) Program

Outside of federal policy, there are other schemes in place designed to achieve consistency within ethics review. One scheme is the Certified IRB Professional (CIP) program, which promotes ethical research and administrative best practice for experienced IRB professionals. Certification is achieved by passing an exam offered by Public Responsibility in Medicine and Research (PRIM&R), and must be renewed every three years.[15] Evidence linking this certification with greater cooperation or outcomes in multi-centre reviews is not available. However, having a network of certified professionals, which is a requirement of many IRBs[16], could be valuable in relation to the acceptance of the new mandate and having IRBs move

[13] http://www.aahrpp.org/apply/resources/evaluation-instrument-for-accreditation https://admin.share.aahrpp.org/Website%20Documents/2015%20Evaluation_Instrument_for_Accreditation%28v2%29.pdf accessed 29 September 2016.
[14] http://www.aahrpp.org/apply/resources/evaluation-instrument-for-accreditation p 36.
[15] http://www.primr.org/certification/cip/faq/ accessed 29 July, 2016
[16] IRB certification becomes industry gold standard. (2010). *IRB Advisor,* Retrieved from http://search.proquest.com/docview/758902890?accountid=12763.

forward with trusting the knowledge base and review of another IRB. This minimum standard of training may also influence trust in approving IRBs where members hold this certification.

4.2.2 United Kingdom

The UK has no single co-ordinated approach to the accreditation of ethics committees or multicentre research activities. The most systematic approach is that of the National Health Service (NHS) Health Research Authority (HRA) which co-ordinates ethics committees and research governance in England. Scotland, Northern Ireland and Wales have their own approval and co-ordinating processes.

The NHS, and Health and Social Care (HSC) in Northern Ireland, play a large role in ethics research review including providing a service that governs NHS Research Ethics Committees (NHS RECs) by using the requirements described in a harmonised UK-wide edition of Governance Arrangements for Research Ethics Committees (GAfREC). Within this framework, each of the four countries have their own portal or process for streamlining multi-centre studies with permissions coordinating functions in place for information sharing across countries where applicable.

HRA Accreditation Scheme for Research Ethics Committees (RECs)

This scheme was established in 2007 with a three year rolling accreditation program to audit the UK RECs against agreed standards outlined in standard operating procedures. As with the NCS and USA assurance frameworks, the UK model is also process focused and does not consider the quality of deliberative review. The key difference with the HRA scheme is that it is mandatory – all NHS RECs must undergo the accreditation process and maintain their accreditation in order to operate. The HRA accreditation scheme also includes the governance arrangements for RECs.

The categories for accreditation are:

- Full accreditation.
- Accreditation with conditions (low risk non-compliance identified requiring an action plan).
- Provisional accreditation (high and low risk issues requiring an action plan.

The HRA publishes biannual reports on the accreditation scheme[17] which make details on RECs audited, the accreditation status conferred and trends in unmet standards (currently membership, training administration, non-compliance with SOPs) publically available. HRA operational managers undertake biannual quality control checks on RECs against the agreed standards. This includes the annual observation of a REC meeting.

In 2009, HRA launched its quality management system and achieved ISO certification against ISO9001:2008 for HRA Quality Assurance Activities.

4.2.3 New Zealand

The Health Research Council (HRC) of New Zealand is the accrediting body for ethics committee in New Zealand (NZ). Although termed an accreditation scheme, the term “approved” ethics committee is used by the HRC in its guidelines. The HRC has approved 11 ethics committees across NZ, a mix of university and health ethics committees.

A key difference between the HRC scheme and the NCS is that the HRC has created some unique levers to incentivise becoming an approved committee. These include:

1. In order for participants to be eligible for compensation from a clinical trial related injury, approval for the research must have been approved by an approved ethics committee.
2. Only approved committees can approve access to the NZ Health Information Service database.
3. The ethics assessment of HRC funded research must be undertaken by an approved committee.

[17] http://www.hra.nhs.uk/documents/2016/05/hra-accreditation-scheme-report-october-2015-march-2016.pdf.

The insurance arrangements and jurisdictional based privacy requirements would not enable (1) or (2) under the NCS. However, a requirement that all NHMRC-funded research must be reviewed by a certified institution would be available to the NHMRC. This approach is likely to drive an increase in certification from the university sector, but may have some regulatory implications.

A number of elements from the HRC guidelines and reporting requirements, that may be of benefit to the NCS, have been identified. These are:

Approval of Ethics Committees

- The HRC requires ethics committees to outline their decision making process (vote, consensus etc. with narrative on how this works in practice). This may provide some, even if limited, insight into the deliberative decision making process of the committee.
- The HRC reviews all policies and procedures and provides suggestions for amendments required before approval is granted. This approach, which is similar to that already carried out under the NCS, could be applied to determine the compliance of certified institutions SOPs with the *National Statement on Ethical Conduct in Human Research* (2007) – updated May 2015.

Re-approval (renewal of certification) of Ethics Committees

- The HRC re-approval documentation is significantly more detailed than that required in the NCS and combines the annual report with the re-approval application. The annual report is used in years one and two of approval, the combined report is used in year three.
- A report from the Chair is required in the application for re-approval. This report includes a summary of committee performance over the approval period, trends in the functioning of the committee and the opportunity to highlight challenges and achievements. The current NCS renewal of certification document does not give much opportunity for narrative or to develop an understanding of the operating conditions of a HREC.
- Committees are asked to provide a summary of changes to policies and procedures over the last three years, including how these changes have impacted the committee (positive or negative).
- The HRC specifically requests details on the assessment time for ethics applications (Time from submission to decision in total).

Annual Report

The HRC annual report requires a Chair's report each year. These reports can then be summarised for the re-approval application. Example topics discussed include workload, resources, changes to policies, institutional environment, difficult areas of review or problem proposals, requests for guidance on specific areas that the ethics committee wishes to put to the HRC. A similar section could be used for ongoing feedback between certified institutions and NHMRC.

Key findings of the literature review

- None of the accreditation schemes reviewed (including a selection of small European Schemes not discussed) included accreditation criteria for the quality of the deliberative review process.
- The AAHRPP accreditation criteria are focused on desired outcomes. This could be used in the NCS to assess the practice of ethics review, how well policies are embedded in an institution and researchers' understanding of the ethics review process.
- There is little advantage, based on the review, for the NCS to move from a certification system to an accreditation system.

5 Consultation Findings – Value and Implementation of the NCS

The findings from the consultation reflect an analysis of both the semi-structured interviews and the survey. Although analysed separately, there was significant overlap in the questions and the findings. Where there was significant difference in views between the survey and the interviews, this difference is highlighted.

5.1 The value of the NCS

The semi-structured interviews and the survey explored the benefits and value of the NCS to certified institutions, sponsors and researchers. Value was not defined and interpretations varied both between and within stakeholder groups. In the semi-structured interviews, stakeholders were asked the following questions:

- What have been the most valuable aspects of the NCS?
- What value has been added to processes or research outcomes?
- Has certification increased trust or reliability in the processes of the certified institution?
- Has certification improved the quality of HREC review processes?

The major benefits associated with the NCS are provided below.

5.1.1 Improved Trust Between Certified Institutions

All interviewed stakeholders reported improved trust between certified institutions. This was reported as the most significant benefit of being a certified institution. Jurisdictions that are not part of NMA and non-certified institutions also recognised the role that certification can play in improving trust in the ethics review processes of reviewing institutions. Certified institutions felt that certification conferred a status of trustworthiness and led to verifiable processes. Some institutions felt that certification was recognition of meeting best practice; however, the majority recognised certification as confirming only that an institution met the minimum acceptable standard as outlined in the assessment criteria. Institutions reported confidence in expediting projects that had approval from another certified institution, even if there were minor matters in consent documentation that would not be preferable to the local HREC.

The improved trust between certified institutions stems from three aspects of the NCS:

1. consistent, robust process of initial certification undertaken by the NHMRC
2. the assurance of a minimum standard of processes that needed to be met prior to certification being awarded to an institution
3. commitment from institutions to the concept of single ethics review and the understanding that acceptance of single ethics review is critical to improving the timelines and overall success of the Australian system of ethics review and approval.

5.1.2 Enhanced Reputation

The impact of the NCS on institutional reputation was considered a minor benefit with a minority of institutions seeking certification for reputational purposes. Universities were more likely to seek certification to demonstrate an equivalent standard to PHOs. A small number of HRECs commented that they believed the quality of certified institutions to be higher and that this had a negative impact on their view of non-certified institutions, particularly with respect to the expertise of universities in HREC review of complex areas such as clinical trials, specifically, those involving medical devices and genetic research. Certification in specific categories such as clinical trials or paediatrics was perceived as beneficial and a recognition of expertise and experience in a particular area.

5.1.3 Improvement in Process and Governance

Approximately half of the institutions interviewed reported that the process of undergoing certification had the tangible benefit of improving internal processes such as reporting, governance and documentation standards. The process of certification also required that institutional management recognised the need to invest resources in the review and improvement of processes in order to meet the minimum standard required to achieve certification.

Certification as a process also forced institutional management to see the HREC and its functions as organisational functions, rather than a stand-alone committee that required minimal resources and attention. Some institutions and HREC representatives reported the certification process was instrumental in integrating HREC functions into organisational management structures.

A small number of institutions reported a need for large-scale process redesign in order to meet the certification standards. However, all felt that this was a necessary and worthwhile exercise that, in turn, resulted in more transparent, robust ethics review processes. Institutions that have been part of jurisdiction-based accreditation or certification schemes reported less change to practice and processes.

While all institutions required some process and documentation changes in order to achieve certification, no institution reported any substantial changes to the deliberative process used by their HREC to review applications.

5.1.4 Additional comments on the value and benefits of the NCS

PHOs viewed the NCS positively, with tangible benefits such as prescribing a minimum required standard to undertake ethics review of multicentre research. Universities saw the in-principle benefits of the NCS and supported the need for increased mutual recognition of ethics approval, but viewed the NCS as of most benefit to PHOs and could not see the practical advantages for them. In general, the perception of the lack of a clear advantage to the institution was a major factor for those institutions electing not to participate in the NCS.

Sponsors reported minimal impact of the NCS on them. Most sponsors interviewed indicated familiarity with the NMA scheme and the jurisdictional “lead committee” model but not specifically with the NCS. Sponsors did not attribute any improvement in review quality, productivity or timeframes to certification. There was a strong view that HREC review times were highly variable and the NCS was of little value unless it included minimum performance indicators for timeliness. Further, although sponsors recognised the reduction in duplication of HREC review in recent years, they attributed this to state-based multicentre review schemes, such as the NMA rather than the NCS. In the survey and interviews, approximately 70% of sponsor respondents called for a “national approach” to the recognition of a single ethics review.

During the consultation, sponsors and researchers did not demonstrate an in-depth understanding of the NCS or its relationship to single ethics review schemes such as NMA, but did recognise a benefit to maintaining a minimum standard of ethical review processes.

Consistency of process and ethics review was a dominant theme in the survey that did not emerge to the same degree in the interviews. This may reflect the views of sponsors and researchers who were the stakeholder groups with the largest number of responses to the survey. Sponsors and researchers were of the view that consistency was a highly desirable requirement of any system of national recognition, but that this had not occurred in practice. Both HREC members and sponsors raised the point that HRECs of certified institutions could reach entirely different outcomes when reviewing the same study. However, it should be noted that consistency in decision-making processes or review outcomes was not an objective of the NCS.

5.2 Implementation of the NCS

The set of questions related to implementation sought to elicit views regarding any challenges with the certification process, whether the roll out of the NCS was consistent with the project objectives, and the positive and negative experiences of implementation of the NCS reported by institutions.

5.2.1 The Certification Process

Institutional stakeholders reported largely positive experiences of the certification process. In particular, stakeholders noted that NHMRC staff were extremely helpful and responsive in the initial certification rounds. The role of certification assessors in enabling quality improvement was overwhelmingly seen as an advantage of certification and one of the most useful and rewarding aspects of the process.

The following positive views of the certification process were also articulated:

- States that are not currently signed up to NMA found the certification process and documentation particularly helpful in developing state-wide criteria for single ethics review processes.
- Increased engagement of senior management in the institution with the HREC members and processes was observed. This was reported to be due to NHMRC certification reporting requirements and the need to engage with the site assessment.
- The need for investment in training was better understood by the institution (in order to retain certification).
- Areas in need of improvement in ethics review processes were highlighted.
- Administrative processes, including improving documentation standards, were sharpened.
- Compliance with the NCS and the National Statement in terms of membership and management of conflicts of interest improved.

In the survey responses, HREC members indicated they were happy with the certification process, with the majority recommending no changes. However, there were divergent views with 50% of research managers and Directors stating that the initial certification process should be improved.

Stakeholders noted that the ability of the HREC to apply the National Statement did not form part of the assessment criteria. This point was raised directly by HREC members and indirectly by sponsors and researchers through comments that the focus was entirely on process rather than consistency or quality of decision-making. One respondent commented:

> *"The certification scheme is more about processes than the ability of a committee to provide ethical review. The competency of a Committee to provide ethical review is more about the people who sit on it than the administrative processes that support it."*

While the omission of the quality of review from the NCS criteria was discussed in-depth, it is important to note that the NCS from inception only included the certification of institutional processes.

5.2.2 Impact on NCS Participants

Participants in the NCS reported varying levels of impact of the NCS certification process and its implementation.

Acceptance of approvals

Institutions with experience in the State-based accreditation systems reported no issues and little practical change in operationalising the NCS and did not report instances in which ethics approval granted by their HREC was not accepted by other certified institutions. However, certified universities, private health organisations and public hospitals from non-NMA jurisdictions reported frustration due to their HREC approvals not being accepted by other certified institutions. This outcome was seen by these institutions as contrary to the intent of the NCS. The feedback on this issue from public hospitals was that, despite certification, there was still uncertainty around the quality of non-public hospital HREC review of research, including clinical drug or device trials, and that the public hospitals were believed to be outside the level of expertise and experience of some institutions' HRECs. Despite this concern, it was notable that the small number of universities interviewed expressed little appetite for conducting ethics review of research such as clinical drug or device trials. An option to address the concerns of PHOs is for the

NHMRC to provide non-PHOs with a limited certification in the clinical trials category that would enable their review of clinical trial interventions other than trials of unapproved therapeutic goods and devices.

Initial Certification process

The majority of feedback on the certification process was that it was useful, worthwhile and that NHMRC staff were very helpful. In addition, the assessor feedback was valued and encouraging. By contrast, the certification process was considered by some to be a protracted process with delays in feedback from the NHMRC.

The purpose and value of the desktop assessment was unclear to some HREC representatives and support staff, although it was noted that it could be useful in identifying inconsistencies.

Renewal of Certification Process

There is limited documentation related to the purpose of the renewal of certification process. It was assumed by institutional stakeholders that the renewal process sought assurance that an institution continued to meet the certification criteria and provided an opportunity to review any changes in institutional policy or documentation (Terms of Reference etc.) that may have been made since certification.

The renewal process was less favourably viewed than the certification process. This may be partly due to confusion with respect to the purpose, timing and value of the renewal process. Institutions reported long delays in communication from the NHMRC during the renewal process. They also reported concerns and confusion around when certification expired as extensions were reported in several instances compared to when an application of renewal was required. Institutions were not clear on the merit of the renewal of certification processes in determining that an institutional had continued to maintain the same process standards as assessed some years earlier.

Annual reporting

The initial annual reporting required of certified institutions produced frustration. HRECs and managers reported concerns regarding:

- the requirement for two reports to NHMRC (one for the registered HREC and one for the certified institution)
- the focus of the report on institutional information rather than information specific to the HREC (which reflected confusion around which body was certified)
- the need to report on the number of studies reviewed in categories (and sub-categories for clinical trials) without providing a way to report on research that fell into more than one category
- annual changes in the data required for the report.

However, there was also recognition that some of these issues have been resolved since the first year of reporting. Most institutions reiterated the importance of predictability of data collection, along with the need for sufficient notice when additional data would be required. Stakeholders made the following comments on the annual reporting process for certified institutions:

- one report was useful and valued by NCS participants
- the data collection was onerous, as institutional databases did not support the level of detail required
- it was unclear if there was a requirement to report changes in membership.

5.2.3 Impact on other stakeholders

Sponsors and researchers reported little to no impact of the NCS on their day-to-day activities. Feedback from sponsors on whether or not certification influenced their choice of reviewing HREC was a point of variation between the survey and the interviews. In the interviews, all sponsors reported that they chose

HRECs based on previous experience and reputation alone. However, in the survey, 23/44 researcher/sponsor respondents indicated that certification influenced HREC choice.

Survey comments indicated that submitting to institutions with certified HRECs was preferable based on perceived advantages related to mutual recognition and timeliness. However, upon further probing, these comments were more related to the use of Lead HRECs rather than certified institutions, emphasising the confusion between certified institutions, which were subject to NCS requirements, and Lead HRECs, which were governed by policy and timeframes at a state level. It was acknowledged that there was considerable overlap between certified institutions and Lead HRECs, which was likely to contribute to the confusion.

5.2.4 Benefits of the tools supporting the certification process

Both the survey and interviews sought to explore if people used the available tools, found at https://hrep.nhmrc.gov.au,[18] as the institution progressed through the initial certification process; if the tools were helpful or useful once certification was obtained; and if NHMRC should make any changes to the tools. It is noted that, since the consultation was completed, NHMRC has advised that the HREP will be decommissioned and information relating to the NCS would be located on the NHMRC website.

The responses to this question indicated the main users of the HREP were research managers and sponsors. Few responses indicated that respondents used the tools and some respondents did not know that the tools existed. The majority of respondents felt that tools and guidance on the NCS should continue to be published but did not provide any specific feedback on the current suite of documents. There were no reports of the tools being used once initial certification was achieved. Research managers were the only group in the survey that held any views on the ongoing development of tools by the NHMRC. Respondents saw the provision of guidance by NHMRC on its instruments as a key responsibility.

5.2.5 Cost Impact of the NCS on Institutions

The cost impact of the NCS on institutions was only raised in the semi-structured interviews and related to the cost to institutions of achieving and maintaining certification. This included costs such as staffing, technology requirements and changes to productivity. There was variation in the costs incurred and resources required to achieve certification. Most institutions reported a need for additional or diverted resources during the initial certification process; only two reported the need to appoint additional staff. Generally, the cost associated with achieving certification was viewed as necessary and a 'cost of doing business'. The annual reporting process was reported as being resource intensive and requiring extensive data gathering. However, one of the perceived benefits of certification was that it enabled institutions to justify the adequate resourcing of the HREC and its professional staff.

There were no reports of additional workload or cost impact on the HREC itself or its members. The time-cost was primarily borne through the professional staff during initial certification and related to ongoing monitoring, submission of annual reports and renewal of certification.

In the survey, institutions were asked whether the NCS had **an impact on the efficiency of HREC management or ethics review processes** at your institution

Category	Yes	No	Did not answer
Manager/Director/Institution (Certified Institution)	12	20	0
Total	**12**	**20**	**0**

[18] In October 2016, NHMRC decommissioned the Human Research Ethics Portal and centralised documentation relevant to the NCS and National Approach on the NHMRC website. Materials related to the NCS can now be found at: https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review-multi-centre-research.

Some of the reported efficiency impacts of certification included:

- raised profile of the ethics office within the institution, with corresponding improved support from senior management
- more focused and efficient ethics and governance reviews, as governance and ethics issues were more clearly separated
- increased trust in accepting non-NMA reviews, resulting in a decrease in duplication
- development of clear guidelines or policies for decision making (e.g. ethics and governance sign-off)
- more efficient SOPs and higher quality policies
- clearer direction to the institution on ways to improve performance
- increased resourcing from the institution
- improved discipline in reporting and capturing data.

6 Consultation Findings on the Future Direction of the NCS

This section outlines the consultation findings on what the NCS could look like in the future and what changes could be made to strengthen and improve the scheme. Every stakeholder was asked to comment on whether or not the NCS should continue and if so, what future iterations of the NCS should include and aim to achieve. Two separate questions were asked during the survey and interviews regarding how the delivery of the NCS could be improved. The two questions were combined for reporting purposes due to the overlap in suggested procedural improvements, structural improvements and overall improvements in the certification model. The certification research categories and certification criteria are also discussed in this section.

6.1 Should the NCS continue?

The response was unanimous* from certified institutions that the NCS should continue. The initial certification program was seen as an important initiative and the review of the program is understood to provide the opportunity to further develop and strengthen the NCS. Non-certified institutions offered no feedback on this question. As discussed further in this section there was much less agreement on what the NCS should assess into the future.

Category	Yes	No	Nil Response
HREC Member (Certified Institution)	27	1*	4
HREC Member (Non-Certified Institution)			
Jurisdictional Representative	3		
Manager/Director/Institution (Certified Institution)	22		
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	40		5
Total	**92**	**1**	**26**

*A single ‘no’ response was indicated in the survey; however, the corresponding comments supported the continuation of the NCS along with a suggestion for improvement.

6.1.1 Who should operate the NCS?

The prevailing view is that the NHMRC should continue to operate the NCS. The NHMRC is responsible for the National Statement and is viewed as the owner of the processes that ensure ongoing compliance with it.

The area for debate is whether the NCS should continue as is, with a panel of expert assessors from the NHMRC; or if the assessment processes should be amended to include an expert panel to provide 'peer review' along with the NHMRC. The survey results show an even split between the two options with the views of HREC members slightly favouring the existing model. As with other questions on the continuation of the NCS, non-certified institutions expressed no view.

Category	NHMRC (as at present)	NHMRC with an expert review panel	Other accreditation or certification body	Nil Response
HREC Member (Certified Institution)	14	11	2	5
HREC Member (Non-Certified Institution)				14
Jurisdictional Representative	2	1		
Manager/Director/Institution (Certified Institution)	10	11	1	
Manager/Director/Institution (Non-Certified Institution)				17
Researcher/Sponsor	17	20	3	5
Total	**43**	**43**	**6**	**41**

In the survey, this question did not address what type of expertise should be included in the expert panel. However, stakeholders provided comments that the panel should extend to include process experts (such as experienced HREC Chairs and managers). During the interviews, it was possible to explore if stakeholders were speaking of the expertise under the current NCS model, or the expertise required to assess institutions in a future iteration of the NCS. Many stakeholders supported amendment to the scope of the NCS to include consideration of deliberative process and application of the National Statement. Should the scope of the NCS change in the future then stakeholders clearly supported membership of the expert panels with experience in HREC process review and/or committee deliberative processes.

The NHMRC plus expert panel model was expected to impose additional resource and organisational burdens on the NHMRC related to selecting and maintaining the expert panel. The perspective of experienced researchers as panel members may also be useful to communicate how processes impact on research in practice. It was suggested that these members could be drawn from the HREC membership of certified institutions.

The consultation findings presented no clear way forward on this option. One suggestion was to reinstate the previously established panel of assessors that the NHMRC can draw on to assist with the certification and renewal processes.

6.2 Feedback on Certification Criteria

The certification handbook outlines the criteria that the Institutions and its HREC(s) will be assessed against. The institution must be able to demonstrate compliance across the following areas:

- Group 1 Assessment criteria based on the NHMRC/ARC/AVCC *National Statement on Ethical Conduct in Human Research* (2007).
- Group 2 Assessment criteria linked to arrangements for conduct of ethical review by the institutional HREC.
- Group 3 Assessment criteria related to training of HREC members and institutional administrative HREC support staff.
- Group 4. Assessment criteria related to process of ethical review of multi-centre research.
- Group 5 Assessment criteria related to ethical review of multi-centre clinical trial proposals or multi-centre clinical interventional research proposals.

- Group 6 Assessment criteria linked to institutional policy and administrative processes supporting ethical review.

An Institution may also seek certification in one or more of the follow research categories:

Justice health	Mental health
Population health and/or public health	Qualitative Research
Clinical Trials (Phase 0, I, II, II or IV)	Clinical intervention other than clinical trials
Other health and medical research	

Institutions can also elect to nominate for certification in research categories for specific populations. Additional specialised assessment review may be required (but is not essential) for certification in these categories:

Children and young people	Women who are pregnant and the human foetus
People highly dependent on medical care who may be unable to give consent	People who are in dependant or unequal relationships
People who may be involved in illegal activities	People with a cognitive impairment, an intellectual disability or a mental illness

This section outlines the findings on how useful stakeholders find the current NCS certification criteria and what amendments, if any should be considered.

6.2.1 Categories of research and certification criteria

The survey and interviews sought information as to whether the current certification categories were relevant and whether institutions should continue to be certified in specific categories of human research.

As shown in the table below, the overall finding in this area of consultation is that stakeholders believe that the current categories of certification are useful and appropriate.

QUESTION – Should the categories of research for which institutions can be certified under the NCS be modified? Modification may include re-labelling, deletion, consolidation or expansion of existing categories or addition of new categories.

Category	Yes	No	No Response
HREC Member (Certified Institution)	9	20	3
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	2	1	
Manager/Director/Institution (Certified Institution)	14	8	
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	11	32	2
Total	**36**	**61**	**36**

However, while there is overall satisfaction with the categories of research, the standard required to be demonstrated in order to be certified in each category remains an area of debate. There was conflicting opinion on the experience and expertise that should be demonstrated in order to be certified in a particular research category.

Institutions in smaller jurisdictions expressed a desire to continue to review the full spectrum of research categories, whilst the opposing view is that there are sufficient HRECs that have extensive experience in reviewing certain research categories and that status to review these categories of research should not be conferred on all institutions. There was strong support for raising the standard to be certified in certain research categories to favour institutions that have demonstrated experience and ongoing access to adequate scientific expertise. Areas such as phase I clinical trials were seen as ethically straightforward but scientifically complex. Conversely, genetic research and bio-banking can be scientifically straightforward but present complex ethical issues. Therefore, it is essential that the institutions have significant training and experience in both ethics and scientific review. HRECs and their support teams

were particularly concerned about the paediatric category. Adult health services wish to recruit young people between 12-18 years of age to a number of studies. These potential participants have different needs than the younger paediatric population, as teenagers become more able to provide consent as they approach the age of 18. A number of institutions have requested certification for the paediatric research category in order to be able to recruit 15-18 year olds to studies in oncology and mental health. A consistent recommendation was that there should be a specific category that allows institutions to be certified to review research involving young people as distinct from paediatric research more generally.

Other concerns around certification in specific research categories stems from an uncertainty around whether an institution would refer proposals for research in categories in which it was not certified, to more experienced HRECs.

Stakeholders proposed the following amendments to the certification categories:

- Data linkage should be included as a separate category as it requires demonstrated understanding of multi-jurisdictional privacy implications.
- Inclusion of low and negligible risk research as a category.
- Devices should be certified based on phase of development.[19]
- Preclinical tests: Lab/Bench testing, animal testing, accelerated wear testing
    - Stage 1: Pilot/First in Man
    - Stage 2: Pivotal and IDE Trials
    - Stage 3: Post Marketing Studies.
- Genetic research and biobanking should be included as separate categories, as research in these areas presents distinct ethical issues. Review of this research should require demonstrated training and understanding of current ethical issues, cross-jurisdictional movement of tissue and data, emerging technologies, risks to participants and benefits of genetic research and biobanking.
- Only defined categories should be included in the certification status. This would mean the removal of the “other” category.
- Qualitative research should not be included as it is a methodology. Rather, institutions should articulate the type of research they routinely review and their expertise in common areas of research submitted for review (as per the National Statement).
- Creation of a certification category for young people that is distinct from paediatric research.
- Categories should align with the national, Human Research Ethics Application (HREA).

6.2.2 Certification of post approval processes including monitoring process

During the semi-structured interviews, all but one HREC representative raised concern that the NCS primarily dealt with the initial approval process and did not provide assurance on the post-approval processes of a certified institution. Stakeholders were of the view that any certification of ethical review processes needed to encompass the capability and capacity to monitor the entire ethical review lifecycle from approval to closure, not just the approval phase. The extension of certification to include post-approval processes was strongly supported by participants. In particular, there was support from HREC members and support staff for standardised post-approval documentation.

Review of the certification criteria indicated that post-approval processes were included in the certification criteria; however, the limited advice in the Certification Handbook was not recognised by stakeholders during the consultation. This finding further supported the overall finding that available tools were poorly

[19] Bourgeois, B “Background to Medical Device Clinical Trials http://www.arcs.com.au/images/presentations/IAC_meeting_presentations/ARCS_Aug_2014_Medical_Device_Clinical_Trials.pdf accessed 4th October 2016.

utilised by institutions and their HRECs. In this sense, it may be necessary to raise awareness of the available tools and to locate them in an easily accessible part of the NHMRC website.

Monitoring of approved research emerged as an area of confusion for stakeholders with regard to what responsibilities sit with the approving HREC and what the responsibility of the sites conducting the research is as part of their governance processes. The NHMRC has previously published the *Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research* (January 2012) which provides guidance on the responsibilities of monitoring in multicentre research. There was no recognition of this document during the consultation, further supporting the poor engagement of institutions with the available tools.

Annual reporting (by the researcher to the HREC) was also raised as an area where the NCS could assist by improving consistency. The use of a single and standard annual reporting form was supported by all stakeholders, however the matter of jurisdictional specific reporting was not addressed.

Stakeholders proposed that certification of post-approval processes could be strengthened by development of:

- Guidance on the expectations of HRECs and institutions regarding monitoring responsibilities. This could be achieved by amending the existing guidance on roles and responsibilities to include examples and case studies.
- A suite of standard documents including the annual report to the approving HREC, amendment/variation forms and SAE notification. This would improve the consistency of information provided. Stakeholders also strongly supported the mandatory use of these forms for certified institutions.
- Certification criteria on the minimum process for approval of amendments and variations.
- Improved communication and awareness-raising of the existing monitoring framework.

6.2.3 Certification in the Review of Low and Negligible Risk (LNR) research

The absence of certification of processes for review of low or negligible risk (LNR) research was raised as an issue by the majority of HRECs during interviews. Ethics review processes for LNR research are outlined in the National Statement and provide institutions with options for non-HREC levels of review. Some institutions comfortably accepted the approval of LNR research from another institution but this approach was not universal. Neither the NCS nor the NMA scheme have considered LNR research until recently.

In practice, there appears to be substantial variation in LNR review processes used by different institutions. Some HRECs declined to use any of the recommended expedited processes, while other institutions had very clear standard operating procedures and requirements for the non-HREC review of LNR research.

While not mentioned during the consultation process, the National Statement does not mandate process requirements for the review of LNR research. The National Statement also provides latitude for some negligible risk research to be exempt from ethics review[20]. The recent amendment of NMA to include all multicentre research has expanded acceptance of ethics review of LNR applications. This has resulted in an increase in the demand on institutions in these jurisdictions to accept the review of an NMA HREC. In turn, this has prompted questions regarding the standards related to processes used for LNR review.

It was recommended that the jurisdictions share their experience in this area with NHMRC and that NHMRC and the jurisdictions work together to develop appropriate certification criteria for LNR research activities. An appropriate amendment to the NCS may be that the NCS certifies all ethics review processes, not just HREC review processes.

[20] National Statement 5.1.8 - Research that carries only negligible risk (see paragraph 2.1.7) and meets the requirements of paragraphs 5.1.22 and 5.1.23 may be exempted from ethical review

6.2.4 Assessment of the quality of HREC review

A frequent criticism of the NCS was the narrow focus on ethics review processes with no scope for assessment of the quality or outcome of the committee deliberations or its compliance with the National Statement. A key finding from this question in the survey and interviews is that there is strong support for the expansion of the assessment criteria beyond the review of process documentation to include evaluation of HREC meetings themselves, or other indicators of quality.

However, while the majority of stakeholders supported the expansion of certification criteria to include measures of quality, they acknowledged the practical challenges in developing useful quality measures applicable to a subjective process.

Should the certification criteria be extended to include measures of quality (of review process, of deliberative process and/or of review outcomes)?

Category	Yes	No	Nil Response
HREC Member (Certified Institution)	21	9	2
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	2	1	
Manager/Director/Institution (Certified Institution)	17	5	
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	36	7	2
Total	**76**	**22**	**35**

In the survey, nine HREC members of certified institutions provided a “no” response to the questions of introducing quality measures. Six of these nine respondents provided comments on the reasons behind their negative response, suggesting:

- too much time would be necessary to complete documentation
- guidance should be provided, but not rigid rules
- the terms of reference and institutional policies should provide sufficient information on the quality of reviews being conducted
- risk of additional workload if criteria are lengthy
- quality measures are too arbitrary
- the current process, which includes regular training of HREC members, is sufficient.

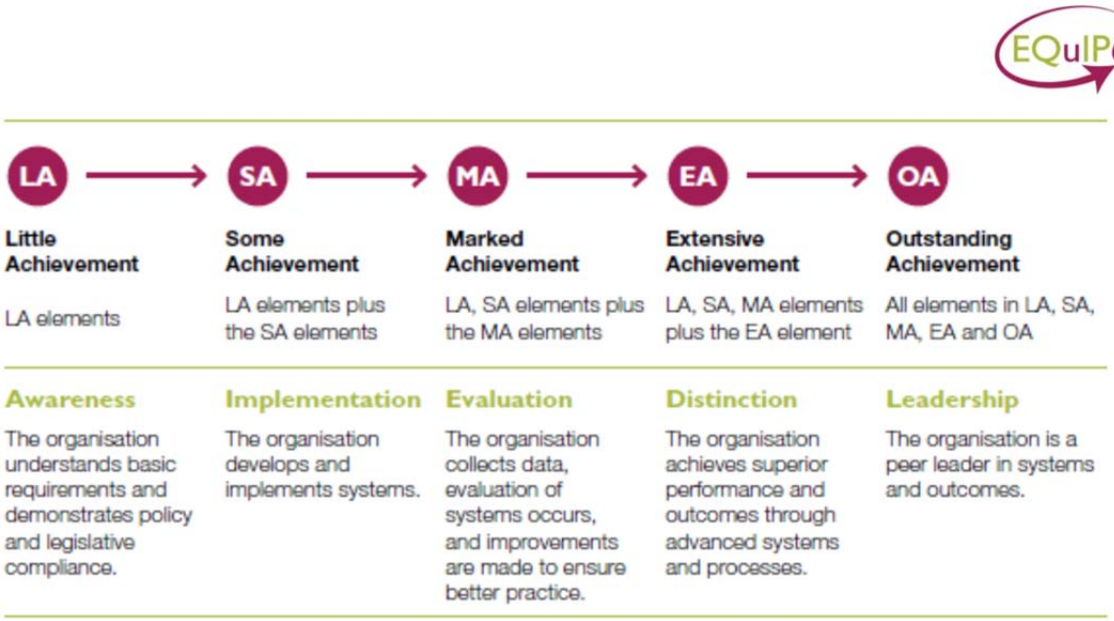
One jurisdiction was also not supportive of introducing quality measures and provided this feedback:

> *“These are difficult concepts to articulate well in certification criteria. Currently, the National Statement provides non-prescriptive guidance at an appropriate level for interpretation. Prescribing such 'quality' measures risks standardising processes leading to a single method of considering ethical matters which may be insusceptible to adaptation as research ethics evolves.”*

In summary, while there was substantial support for a quality framework, stakeholders agreed that developing this framework would be difficult and offered few ideas regarding what quality assessment criteria might include. The criteria that were suggested focused on expanding the NCS to assess the consistency of processes and in the interpretation and application of the National Statement. During the consultation, stakeholders often referenced consistency, timeliness and efficiency between institutions as examples of quality. While these may not be widely considered as quality measures (and are technically still process orientated), they are included in this discussion as the stakeholders understanding of quality measures in the ethics review context.

Example Quality Assessment Frameworks

A number of HREC and institutional representatives expressed a view that the minimum standard of certified processes should be raised and that the NCS could recognise that some institutions have more sophisticated systems and an ongoing focus on process improvement. Some HRECs and managers saw the current criteria as binary and unable to recognise areas of excellence and innovation. Introducing a scale that recognises meeting minimum requirements through to outstanding achievement provides institutions with a framework for ongoing quality improvement. Certified public hospitals used the example of the Australian Council on Healthcare Standards (ACHS) as a possible model framework. The ACHS framework has mandatory criteria that must achieve a minimum of marked achievement in each standard to achieve accreditation.[21]



The criterion rating format will assist organisations to better understand how the elements can support continuous improvement.

The National Safety and Quality Standards[22] use a scale to assess performance against criteria of:

- Not met – the actions required have not been achieved
- Satisfactorily met – the actions required have been achieved
- Met with merit – in addition to achieving the actions required, measures of good quality and a higher level of achievement are evident. This would mean a culture of safety, evaluation and improvement is evident throughout the organisation, and that the level of performance is sustainable.

Stakeholders suggested the following possible mechanisms for assessing quality of HREC deliberative processes and improving consistency:

- A forum to discuss areas of difference in the application of the National Statement during ethics review. This could be hosted by the NHMRC or by interested institutions who wish to participate in the discussion. The discussion could take place as part of existing fora such as the Australasian Ethics Conference, under the leadership of the Ethics Special Interest Group of the Australasian Research Management Society.
- Clear reference to the National Statement in minutes and correspondence to the applicant researcher as a matter of practice.

[21] http://www.achs.org.au/media/114456/equip6_information_pack_final.pdf.
[22] https://www.safetyandquality.gov.au/wp-content/uploads/2014/03/Accreditation-Workbook-for-Mental-Health-Services-March-2014.pdf.

- A requirement that certified institutions demonstrate ongoing compliance with certification criteria, including measures of efficiency such as timeliness of review.
- Monitoring of internal compliance against the National Statement and Standard Operating Procedures (SOPs). This could include a requirement that institutions publish their SOPs and provide a mechanism for researchers to report HREC non-compliance with these SOPs and the National Statement to the institution. Sponsors, in particular, felt that existing complaint and escalation procedures for many institutions were difficult to locate.
- Use of an NHMRC managed audit involving a small number of certified institutions to evaluate consistency of review processes, including timeframes and feedback from HRECs to researchers. The resulting data could be used to facilitate dialogue between the reviewing HRECs and to provide data on areas of consistent or inconsistent application of the National Statement.
- Standardisation of ethics review through consideration of one or more specific applications to a random selection of certified institutions. This would require researchers and/or sponsors to agree to submit the proposal/s to multiple HRECs at a frequency that is logistically manageable.

Any of these approaches could be piloted by a small number of institutions prior to their inclusion as part of the NCS.

Arguments against quality measurement of the HREC deliberative process

A small number of stakeholders cautioned against the introduction of criteria to assess the quality of the HREC review process. The concerns centred around the increased administrative burden of reporting on quality measures and the fact that the ethics review process is subjective and variable by its nature. Stakeholders questioned the value of applying standard quality measures to a subjective process. Some HREC members were worried that the introduction of quality measures would reduce the latitude that HRECs currently have in decision-making.

The practical difficulties in introducing quality measures for subjective processes were cited by some stakeholders as the fundamental reason why such processes should not be subjected to evaluation of the quality of ethics review or deliberative processes.

6.2.5 Proposed new requirements for certified institutions

These proposed requirements were tested in interview and in the survey. While HREC members and research managers were supportive of all the proposed changes, sponsors and researchers, in particular, proposed amendment in these areas.

The proposed new requirements discussed in this section are:

1. the requirement that all certified institutions have publically available terms of reference and standard operating procedures
2. that certified institutions are required to use standard documents as mandated by the NHMRC
3. that certified institutions must accept the review conducted by the HREC of another certified institution (assuming they are certified in the relevant category)
4. that certification includes a requirement to demonstrate the ability to meet an accepted benchmark for timely review.

These proposed requirements were described by stakeholders as “levers”. The certification criteria can introduce levers to improve the consistency of ethics review between certified institutions. Sponsors and researchers were supportive of this approach as consistency and standardisation would reduce administrative burden when working across multiple institutions.

1. **Certified institutions must have publicly available Terms of Reference and Standard Operating Procedures**

There was support from stakeholders for institutions to have terms of reference and standard operating procedures and for these to be publically available. It is unlikely that the content of these documents could be standardised; however, the NHMRC could consider providing comprehensive templates similar to those used in the NMA jurisdictions. These templates could outline the minimum areas where institutions must have SOPs. The certification or renewal of certification process could then test internal consistency with published SOPs at a site visit or through survey of researchers, HREC members and relevant institutional stakeholders.

2. **Certification requires the use of standard documents**

This requirement was supported by the consultation responses. Sponsors and researchers are the strongest supporters of this requirement; however, the majority of HREC members and research managers also agreed. This requirement includes:

- use of standard post approval forms including progress/annual reporting form to the approving HREC and amendment/variation requests
- use of standard information sheets and consent forms such as those located at www.nationalpicf.com.au
- use of previously developed standard template letters and forms.

There was support for the mandated use of a national application form from sponsors, researchers and PHO based HRECs. This requirement would require further consultation with the university sector. Many universities have invested heavily in their forms and processes and the requirement to use the national form is likely to be a disincentive to certification.

3. **Certified institutions must accept the review conducted by the HREC of another certified institution**

This requirement was strongly supported by sponsors and researchers and over half of the research managers and HREC members from certified institutions. While support was not unanimous (three jurisdictions that completed the survey provided a “no” response to this question), the introduction of this criterion would create leverage for efforts to reduce unnecessary duplication of review. However, if introduced, this criterion would need to be accompanied by corresponding mechanisms to resolve complaints from and differences of opinion amongst certified institutions. This requirement of certification was identified by those that supported it as being central to the success of any mutual recognition model.

4. **Certification includes a requirement to meet an accepted benchmark for timely review.**

This reform was strongly supported, particularly by sponsors, and is already in place in jurisdictions that are signatories to the NMA scheme. Benchmarks could be established for time-to-approval consistent with existing measures. In the first instance, turnaround times would be self-reported as part of the annual reporting process. This is to accommodate for the potential barrier that not all jurisdictions and institutions have system-level IT solutions.

Despite the strong support for certified institutions to meet review timeframes, interviews with jurisdictional and NHMRC stakeholders identified significant challenges to this requirement in practice. The introduction of time-based benchmarks for HREC review has the potential for conflict with NMA requirements on timeframes. Non-NMA jurisdictions may also have timeliness measures but these may be different to NMA. There is also the possibility of duplication of data collection, assessment and monitoring if both jurisdictions and NHMRC require evidence of review timeframes. It was also suggested that this proposed criterion makes incorrect assumptions that all jurisdictions have agreed benchmarks on review timeframes.

Despite the strong support from stakeholders for expanding the NCS to include measures of timeliness of review, this proposal will require significant discussion with the jurisdictions on the practicalities of implementation and the potential for duplication and increased workload for institutions.

6.3 Suggested Improvements to the certification and renewal processes

Stakeholder experience of the value and implementation process of the NCS has been discussed. The current NCS is considered by stakeholders to be valuable and reasonable to implement at an institutional level. Although the feedback was positive, a number of suggestions for improvements to the certification, renewal and reporting processes were made.

The key finding for future certification rounds and for currently certified institutions is that it is critical to have a transparent certification program. This includes a consistent period of certification, clear understanding of how long a renewal lasts for and a clear schedule of proposed site visits. Institutions are currently unclear on whether a site visit takes place every three years, five years or only at initial certification and never again. No timeframes for site visits were proposed but examples can be drawn from the international models outlined in the literature review.

The most frequent suggestion for improvement of the initial site visit was to expand the certification process to include the observation of a HREC meeting by the NHMRC assessment panel. This is consistent with the interview findings, with feedback from HRECs being that the current assessment process fails to assess the most important role of the HREC: the deliberative process.

The process of certification renewal was seen by stakeholders as an opportunity for improvement with the following suggested improvements:

- NHMRC should establish internal processes to issue reminders to institutions on the imminent expiry of their certification
- NHMRC should improve communication of processes and timeframes for the renewal process as institutions reported long delays in communication from NHMRC
- the renewal process should focus on ongoing compliance with the National Statement and ongoing improvement in institutional processes.

Stakeholders reported mixed experiences on the annual reporting process to the NHMRC. There was acknowledgement that the process had improved, however some still found the reporting onerous and time consuming. However, two points of improvement emerged:

- The importance of predictability in data collection was reiterated by most institutions along with the need for sufficient notice where additional data will be required.
- The current annual report to the NHMRC did not accommodate research that fitted into more than one category. Data collection could include total number of studies reviewed, number in each category and the number that was considered in multiple categories. The forms needed to accommodate that the numbers reviewed may be less than the sum of the categories.

6.4 Certification Tools and Communication with Certified Institutions

The feedback on the tools available in the HREP indicated low engagement with the available resources. Throughout the consultation, generally, it was apparent that stakeholders were not aware of existing tools, frameworks and advice. This was apparent as many of the suggestions for improvement were already addressed in the Certification Handbook or other documentation. This indicated an opportunity for improved communication between the NHMRC and certified institutions to ensure they were aware of the available tools and resources.

The following were proposed by stakeholders as useful tools to support the certification process and certified institutions on an ongoing basis:

- Reinstate the ethics conference last held in 2007 as a wide forum for updates.
- Continue to hold the annual meeting of Chairs and Executive Officers of certified institutions.
- NHMRC to conduct roadshows where new programs or initiatives are being rolled out, for example when HoMER was first introduced.

- Provide a flowchart or other document on how the state based systems interact with the NCS.
- Update the current portal, as the draft consent documentation is out of date and references are still made to HoMER in some of the linked documents.
- Make the portal easier to find as the links are not easy to find on the NHMRC website.
- NHMRC to publish examples of “best practice” identified during the certification site visit.
- Increase promotion of the NCS and its benefits with clear communication that the NCS has no day-to-day negative impact on researchers. This could involve engaging with certified institutions to promote the benefit of certification.

7 Other consultation findings

7.1 The role of registered HRECs and certified institutions

This consultation found that there is an appetite amongst stakeholders to continue to improve the system of ethics review. In parallel to the discussion over the future of certification of institutions, the scheme for registration of HRECs was also the source of extensive discussion, in particular the question of whether a minimum quality standard should apply to registered HRECs.

Some stakeholders were generally unclear regarding the difference between registered-HRECs and certified institutions. This lack of clarity was exacerbated by the fact that, in some jurisdictions, a HREC could be registered with NHMRC and accredited by the jurisdiction, but not part of an institution that was certified under the NCS. Unique examples of this were presented in one jurisdiction.

With the focus of the NCS on demonstrating compliance and minimum standards, it became increasingly unclear what the benefits of retaining the HREC registration process were, other than to meet the current regulatory requirement of the *Therapeutic Goods Act 1989* (Cth).

The main concern raised was the risk of a two-tier system where the standard for registered HRECs to operate was very low. The suggested approach was to “beef up” the minimum standards for registration and require all HRECs to demonstrate compliance with the certification criteria. The selection bias on these comments must be noted as the consultation processes specifically targeted certified institutions.

8 Options for Improving the NCS

This review and evaluation of the NCS highlighted many different views and opportunities for improvement. The lists below represent the highest priority and potentially feasible options for implementation from the consultation findings.

Options for improvement of the NCS in the short term

- NHMRC to establish a clear certification cycle. This cycle should clearly state how long the initial certification period is, how long certification can be renewed for and how often the full certification process, including site visit, takes place. According to the literature, a five-year certification cycle may be reasonable with an interim review/renewal at three years. This timeframe will be dependent on available NHMRC resources.
- NHMRC to introduce a certification category and criteria specific to research involving young people.
- Removal of the option to be certified in “other” or non-specific categories.
- Extending the scope of the NCS to review and certify all research ethics review process of an institution; This change in scope will capture the review processes of low and negligible risk research.
- NHMRC to provide a suite of standard forms associated with post approval and monitoring processes.

- NHMRC to consider introducing a requirement for certified institutions to use standard forms for post approval processes.
- Introducing attendance at a HREC meeting as part of the on-site certification assessment.
- NHMRC to provide a “best practice standard operating procedures” template for certified HRECs.
- Amend the certification criteria to ensure that terms of reference and standard operating procedures (including any specified timeframes) are publically available.
- Develop a communication strategy to improve ongoing engagement of certified institutions with available tools and resources.
- Continue with the annual meeting of certified institution HREC Chairs and Executive officers and promote the NCS in forums outside of those attended by certified institutions.

Options for improvement of the NCS in the longer term

- Introduction of additional ethically distinct categories of research as required, eg. Early phase clinical trials, paediatric research and data linkage.
- Introduction of a requirement for certified institutions to use standard forms for approval and post approval processes.
- Reintroduction of the previously established panel of expert assessors; this panel could be used to supplement independent expertise available for site visits.
- Expansion of the scope of the NCS to assess consistency between certified institutions.
- Introduction of a requirement that certified institutions must accept the review of other certified institutions.

9 Appendices

9.1 Questions for Semi-Structured Interviews

Evaluation Questions - National Certification Scheme

Evaluation Form	Issues Explored	HRECs	HREC Admin/Research Directors	Jurisdictions	Researchers	Non-NMA Jurisdictions/HRECs
	1. Has the program achieved what it set out to achieve?	What have been the most valuable aspects of the scheme? What value has been added to research and the ethics assessment process from certified committees?	What do you see as the most valuable aspects of the scheme? What value has been added to research and the ethics assessment process from certified committees?	What do you see as the most valuable aspects of the scheme? What value has been added to research and the ethics assessment process from certified committees?	What do see as the most valuable aspects of the scheme? What value has been added to research and the ethics assessment process from certified committees?	What do see as the most valuable aspects of the scheme? What value has been added to research and the ethics assessment process from certified committees?
		Has certification of your institution's ethics review processes provided assurance to those seeking or accepting the HREC's ethics review that:	Has certification of your institution's ethics review processes provided assurance to those seeking or accepting the HREC's ethics review that:		Do you think that certification of your institution's ethics review processes provided assurance to those seeking or accepting the HREC's ethics review that:	Has certification of your institution's ethics review processes provided assurance to those seeking or accepting the HREC's ethics review that:
		a. There is greater reliability and/or higher standards in the processes used for ethics review over that offered by institutions that are not certified;	a. There is greater reliability and/or higher standards in the processes used for ethics review over that offered by institutions that are not certified;		a. There is greater reliability and/or higher standards in the processes used for ethics review over that offered by institutions that are not certified;	a. There is greater reliability and/or higher standards in the processes used for ethics review over that offered by institutions that are not certified;
		b. The HREC/institution conducting the ethics review has access to	b. The HREC/institution conducting the ethics review has access to		b. The HREC/institution conducting the ethics review has access to	b. The HREC/institution conducting the ethics

		greater or more reliable expertise; and	greater or more reliable expertise; and		greater or more reliable expertise; and	review has access to greater or more reliable expertise; and
		c. The HREC engages in a higher quality of deliberative ethical review	c. The HREC engages in a higher quality of deliberative ethical review	OR - what is your view of the scheme? What are the barriers to being part of it? How might these be addressed?	c. The HREC engages in a higher quality of deliberative ethical review	c. The HREC engages in a higher quality of deliberative ethical review
	2. Effect of the NCS on your business?	what has been your experience of being a certified HREC? What have been the challenges? What works well?	What has been your experience of operating a certified HREC? What have been the challenges? What works well?	How does the NCS interact with jurisdictional processes or additional requirements for certification of HRECs?	What has been your experience in applying for approval from a certified HREC and in using this approval at other site?	
			What have been your experiences of using the reviews of Certified HRECs? What have been the challenges, what works well?	Have any issues emerged from accepting HREC reviews from other jurisdictions?		What have been your experiences of using the reviews of Certified HRECs? What have been the challenges, what works well?
	3. Is delivery consistent within the program	included in analysis from questions on implementation	included in analysis from questions on implementation	included in analysis from questions on implementation	included in analysis from questions on implementation	
	4. How could delivery of the scheme be improved	What communication from the NHMRC was useful (consultation, newsletters etc.) during the certification process?	What communication from the NHMRC was useful (consultation, newsletters etc.) during the certification process?	what communication from the NHMRC was useful (consultation, newsletters etc.) to keep you abreast of the scheme?	What communication from the NHMRC was useful (consultation, newsletters etc.) to keep you abreast of the scheme?	What communication from the NHMRC was useful (consultation, newsletters etc.) to keep you abreast of the scheme?
		What would have helped in preparing for application for certification or	What would have helped in preparing for application for certification or			

		implementation of suggested improvements?	implementation of suggested improvements?			
		Has the scheme improved operational efficiency?	Has the scheme improved operational efficiency?	Has the scheme improved operational efficiency?	Has the scheme improved operational efficiency?	
		Has the scheme improved the quality of ethics review?	Has the scheme improved the quality of ethics review?	Has the scheme improved the quality of ethics review?	Has the scheme improved the quality of ethics review?	
	5.Is the program being implemented as planned?		What is your institutions view on accepting reviews of other HRECs? Do you have any criteria that this review needs to meet?	What was your experience of implementing NCS? E.g. what challenges arose that were unique to your jurisdiction? Was there a decrease in workload? Has trust between HRECs/Institutions improved (and how measured?)	Has there been a reduction in workload for submitting HREC applications for multicentre studies?	
	6. Future Direction of NCS	What are the benefits to maintaining the scheme? Should the scheme continue in its current format? If not, what are some aspects that could be improved or amended?	Should the scheme continue? What are the benefits to maintaining the scheme?	Should the scheme continue? What are the benefits to maintaining the scheme?	Should the scheme continue? What are the benefits to maintaining the scheme?	Should the scheme continue? What are the benefits to maintaining the scheme?

		For example: Should the National Certification Scheme only certify the institutional processes for ethics review or should it be expanded to include an assessment of the quality of the deliberative processes used by the body conducting the review and/or the outcomes of those reviews? If so, how?	Should the National Certification Scheme only certify the institutional processes for ethics review or should it be expanded to include an assessment of the quality of the deliberative processes used by the body conducting the review and/or the outcomes of those reviews? If so, how?	Should the National Certification Scheme only certify the institutional processes for ethics review or should it be expanded to include an assessment of the quality of the deliberative processes used by the body conducting the review and/or the outcomes of those reviews? If so, how?	Should the National Certification Scheme only certify the institutional processes for ethics review or should it be expanded to include an assessment of the quality of the deliberative processes used by the body conducting the review and/or the outcomes of those reviews? If so, how?	Should the National Certification Scheme only certify the institutional processes for ethics review or should it be expanded to include an assessment of the quality of the deliberative processes used by the body conducting the review and/or the outcomes of those reviews? If so, how?
		Should institutions continue to be certified in, or to review, specific categories of human research? If so:	Should institutions continue to be certified in, or to review, specific categories of human research? If so:	Should institutions continue to be certified in, or to review, specific categories of human research? If so:	Should institutions continue to be certified in, or to review, specific categories of human research? If so:	Should institutions continue to be certified in, or to review, specific categories of human research? If so:
		a. Who should determine what those categories should be?	a. Who should determine what those categories should be?	a. Who should determine what those categories should be?	a. Who should determine what those categories should be?	a. Who should determine what those categories should be?
		b. How should the relevant categories be determined?	b. How should the relevant categories be determined?	b. How should the relevant categories be determined?	b. How should the relevant categories be determined?	b. How should the relevant categories be determined?
		c. Are the current categories appropriate and useful to users of the National Certification Scheme?	c. Are the current categories appropriate and useful to users of the National Certification Scheme?	c. Are the current categories appropriate and useful to users of the National Certification Scheme?	c. Are the current categories appropriate and useful to users of the National Certification Scheme?	c. Are the current categories appropriate and useful to users of the National Certification Scheme?
		d. What should designation in one or more of the categories	d. What should designation in one or more of the categories	d. What should designation in one or more of the categories	d. What should designation in one or more of the categories	d. What should designation in one or more of the categories

		mean to users of the certified institution?	mean to users of the certified institution?	mean to users of the certified institution?	mean to users of the certified institution?	mean to users of the certified institution?
		Would you strengthen the certification requirements/processes to better achieve objectives? E.g. Condition of certification that an institution must accept a review from another certified institution's HREC. What would be the benefit?	Would you strengthen the certification requirements/processes to better achieve objectives? E.g. Condition of certification that an institution must accept a review from another certified institution's HREC. What would be the benefit?		Would you strengthen the certification requirements/processes to better achieve objectives? E.g. Condition of certification that an institution must accept a review from another certified institution's HREC. What would be the benefit?	
		How would you change or improve the scheme? (specific aspects/current components)	How would you change or improve the scheme? (specific aspects/current components)	How would you change or improve the scheme? (specific aspects/current components)	How would you change or improve the scheme? (specific aspects/current components)	How would you change or improve the scheme? What changes would you like to see before your HREC/Jurisdiction joined the scheme?
	7. Have the needs of those serviced by the program been achieved?	How useful where the supporting tools such as the website on the HREP, guidelines, standardised forms and templates? How did you use them?	How useful where the supporting tools such as the website on the HREP, guidelines, standardised forms and templates? How did you use them?	Did you implement the standard forms and templates available on the HREP portal?		
	8. Are there any unintended outcomes?	Were there any unanticipated outcomes from being a certified HREC or from conducting reviews e.g. Did you get more applications to review?	Were there any unanticipated outcomes from being a certified HREC	Were there any unanticipated outcomes that impacted ethics review or the management of state wide processes/data management?		Were there any unanticipated outcomes or feedback as a result of not accepting the review of certified HRECs?

	9. Is the program cost effective	What was the cost of implementation and maintained? (time, staff, process or technology improvement)	What was the cost of implementation and maintained? (time, staff, process or technology improvement)	What was the cost of implementation and maintained? (time, staff, process or technology improvement)	What was the cost using a certified HREC? (additional workload, time, staff, process or technology improvement)	Is there a cost of not being involved in the NCS/NMA?

9.2 Survey Results

Survey Overall Response:

Category	Number
HREC Member (Certified Institution)	32
HREC Member (Non-Certified Institution)	14
Jurisdictional Representative	3
Manager/Director/Institution (Certified Institution)	22
Manager/Director/Institution (Non-Certified Institution)	17
Researcher/Sponsor	45
Total	**133**

Question 1A: Are you aware of the existence of the NHMRC National Certification Scheme (NCS) that is used to certify the ethical review processes of an institution for review of multi-centre research?

Category	Yes	No	Did not answer
HREC Member (Non-Certified Institution)	12	2	0
Manager/Director/Institution (Non-Certified Institution)	17	0	0
Researcher/Sponsor	40	5	0
Total	**69**	**7**	**0**

Question 1.1A: Are you aware of the requirements associated with an institution obtaining certification?

Category	Yes	No	Did not answer
HREC Member (Non-Certified Institution)	9	3	2
Manager/Director/Institution (Non-Certified Institution)	12	5	0
Researcher/Sponsor	20	20	5
Total	**41**	**28**	**7**

QUESTION 1B: Are there benefits to your HREC participating in the NHMRC National Certification Scheme (NCS)?

Category	Yes	No	Did not answer
HREC Member (Certified Institution)	28	4	0
Total	**28**	**4**	**0**

QUESTION 1C: Are there benefits to your institution participating in the NHMRC National Certification Scheme (NCS)?

Category	Yes	No	Did not answer
Manager/Director/Institution (Certified Institution)	20	2	0
Total	**20**	**2**	**0**

QUESTION 2A: If your institution has had any interactions with the National Certification Scheme, has that interaction increased your level of confidence in the ethics review conducted by certified institutions?

Category	Yes	No	Not Applicable
Manager/Director/Institution (Certified Institution)	5	3	9
Total	**5**	**3**	**9**

QUESTION 2B: If your HREC has had any interactions with the National Certification Scheme (e.g. received an application previously approved by a certified institution's HREC) has that interaction increased your level of confidence in the ethics review conducted by certified institutions?

Category	Yes	No	Not Applicable
HREC Member (Non-Certified Institution)	4	5	5
Total	**4**	**5**	**5**

QUESTION 2C: Does the operation of the NCS influence which HREC you apply to for the ethical review of proposed multi-centre research?

Category	Yes	No	Did not answer
Researcher/Sponsor	23	21	1
Total	**23**	**21**	**1**

QUESTION 2D: Has certification had a measurable impact upon the efficiency of the HREC management or ethical review processes at your institution?

Category	Yes	No	Did not answer
Manager/Director/Institution (Certified Institution)	12	20	0
Total	**12**	**20**	**0**

QUESTION 2E: Has the NHMRC National Certification Scheme (NCS), which is used to certify the ethical review processes of institutions for review of multi-centre research, had a measurable impact on the review processes in your jurisdiction?

Category	Yes	No	Did not answer
Jurisdictional Representative	2	1	0
Total	**2**	**1**	**0**

QUESTION 3: The current certification criteria (outlined in Appendix 9.1 of the Certification Handbook) focuses on the institutional processes of ethical review for multi-centre research. Are these criteria appropriate and sufficient?

Category	Yes	No	Did not answer
HREC Member (Certified Institution)	27	4	1
Jurisdictional Representative	1	2	0
Manager/Director/Institution (Certified Institution)	13	9	0
Researcher/Sponsor	37	7	1
Total	**78**	**22**	**2**

QUESTION 4: WHICH OF THE FOLLOWING SHOULD BE A CONDITION OF CERTIFICATION?

Agreement to use standardised Terms of Reference and Operating Procedures

Category	Agree	No Response
HREC Member (Certified Institution)	28	4
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative		3
Manager/Director/Institution (Certified Institution)	16	6
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor	36	9
Total	**80**	**53**

Agreement to only use or accept an accepted standard application form (e.g. National Ethics Application Form/Human Research Ethics Application) for submission of multi-centre research proposals for ethical review

Category	Agree	No Response
HREC Member (Certified Institution)	22	10
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative	2	1
Manager/Director/Institution (Certified Institution)	16	6
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor	38	7
Total	**78**	**55**

Agreement to use standard templates for Participant Information and Consent Forms

Category	Agree	No Response
HREC Member (Certified Institution)	16	16
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	13	9
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor	37	8
Total	**67**	**66**

Agreement to use standard forms for post-approval amendments of research projects and/or annual reporting

Category	Agree	No Response
HREC Member (Certified Institution)	18	14
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	14	8
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor	35	10
Total	**68**	**65**

Agreement to accept the review conducted by an HREC of another certified institution

Category	Agree	No Response
HREC Member (Certified Institution)	22	10
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative		3
Manager/Director/Institution (Certified Institution)	14	8
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor	38	7
Total	**74**	**59**

Agreement to meet an accepted benchmark for timely review

Category	Agree	No Response
HREC Member (Certified Institution)	23	9
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative	2	1
Manager/Director/Institution (Certified Institution)	18	4
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor	34	11
Total	**77**	**56**

None of the above

Category	Agree	No Response
HREC Member (Certified Institution)	1	31
HREC Member (Non-Certified Institution)		14
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	1	21
Manager/Director/Institution (Non-Certified Institution)		17
Researcher/Sponsor		45
Total	**3**	**130**

QUESTION 5: Should the certification criteria (outlined in Appendix 9.1 of the Certification Handbook) be extended to include measures of quality (of review process, of deliberative process and/or of review outcomes)?

Category	Yes	No	No Response
HREC Member (Certified Institution)	21	9	2
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	2	1	
Manager/Director/Institution (Certified Institution)	17	5	
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	36	7	2
Total	**76**	**22**	**35**

QUESTION 7: Are there any categories of research that require additional assessment before certification should be granted to institutions (e.g. Paediatric research or Phase 0/1 clinical trials)?

Category	Yes	No	No Response
HREC Member (Certified Institution)	10	19	3
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	1	2	
Manager/Director/Institution (Certified Institution)	15	7	
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	24	19	2
Total	**50**	**47**	**36**

QUESTION 8: The current process for certification involves a desktop review of submitted documentation, an on-site assessment and a follow-up report. Do you recommend any changes to the initial certification process?

Category	Yes	No	No Response
HREC Member (Certified Institution)	3	25	4
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative			3
Manager/Director/Institution (Certified Institution)	10	12	
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor			45
Total	**13**	**37**	**83**

QUESTION 9: Are you aware that NHMRC developed a suite of tools and template documents to support certified institutions? See https://hrep.nhmrc.gov.au/toolbox for further details.

Category	Yes	No	No Response
HREC Member (Certified Institution)			32
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	3		
Manager/Director/Institution (Certified Institution)	19	2	1
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	26	17	2
Total	**48**	**19**	**66**

QUESTION 9.1: Have you found these tools useful? IF YES TO Q9

Category	Yes	No	No Response
HREC Member (Certified Institution)			32
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative			3
Manager/Director/Institution (Certified Institution)	17	2	3
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	18	6	21
Total	**35**	**8**	**90**

QUESTION 10: Should NHMRC continue to develop and provide such tools to support certified institutions?

Category	Yes	No	No Response
HREC Member (Certified Institution)			32
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	2	1	
Manager/Director/Institution (Certified Institution)	22		
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	43		2
Total	**67**	**1**	**65**

QUESTION 11: Do you think the National Certification Scheme should continue?

Category	Yes	No	No Response
HREC Member (Certified Institution)	27	1	4
HREC Member (Non-Certified Institution)			14
Jurisdictional Representative	3		
Manager/Director/Institution (Certified Institution)	22		
Manager/Director/Institution (Non-Certified Institution)			17
Researcher/Sponsor	40		5
Total	**92**	**1**	**40**

QUESTION 12: Who should operate the NCS? (Please select ONE option)

Category	NHMRC (as at present)	NHMRC with an expert review panel	Other accreditation or certification body	No Response
HREC Member (Certified Institution)	14	11	2	5
HREC Member (Non-Certified Institution)				14
Jurisdictional Representative	2	1		
Manager/Director/Institution (Certified Institution)	10	11	1	
Manager/Director/Institution (Non-Certified Institution)				17
Researcher/Sponsor	17	20	3	5
Total	**43**	**43**	**6**	**41**

QUESTION 13: All HRECs registered with NHMRC are required to meet minimum registration criteria (see www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs). Should registered HRECs, as with certified institutions, also be required to demonstrate that their processes meet a minimum standard in order to review any of the following categories of research

Phase 0 and First Time in Humans clinical trials

Category	Yes	No Response
HREC Member (Certified Institution)	19	13
HREC Member (Non-Certified Institution)	11	3
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	19	3
Manager/Director/Institution (Non-Certified Institution)	6	11
Researcher/Sponsor	32	13
Total	**88**	**45**

Early phase clinical trials (i.e. Phase 0 and Phase 1)

Category	Yes	No Response
HREC Member (Certified Institution)	18	14
HREC Member (Non-Certified Institution)	9	5
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	18	4

Manager/Director/Institution (Non-Certified Institution)	6	11
Researcher/Sponsor	32	13
Total	**84**	**49**

Clinical trials of devices

Category	Yes	No Response
HREC Member (Certified Institution)	15	17
HREC Member (Non-Certified Institution)	9	5
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	15	7
Manager/Director/Institution (Non-Certified Institution)	7	10
Researcher/Sponsor	26	19
Total	**73**	**60**

All clinical trials of medical interventions

Category	Yes	No Response
HREC Member (Certified Institution)	12	20
HREC Member (Non-Certified Institution)	10	4
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	14	8
Manager/Director/Institution (Non-Certified Institution)	10	7
Researcher/Sponsor	25	20
Total	**72**	**61**

Trials of non-medical interventions

Category	Yes	No Response
HREC Member (Certified Institution)	10	22
HREC Member (Non-Certified Institution)	7	7
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	10	12
Manager/Director/Institution (Non-Certified Institution)	4	13
Researcher/Sponsor	18	27
Total	**50**	**83**

Complex genetic research

Category	Yes	No Response
HREC Member (Certified Institution)	17	15
HREC Member (Non-Certified Institution)	9	5
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	16	6
Manager/Director/Institution (Non-Certified Institution)	6	11
Researcher/Sponsor	31	14
Total	**80**	**53**

Paediatric research

Category	Yes	No Response
HREC Member (Certified Institution)	15	17
HREC Member (Non-Certified Institution)	8	6
Jurisdictional Representative	1	2
Manager/Director/Institution (Certified Institution)	13	9
Manager/Director/Institution (Non-Certified Institution)	5	12
Researcher/Sponsor	29	16
Total	**71**	**62**

Registries and data linkage research

Category	Yes	No Response
HREC Member (Certified Institution)	10	22
HREC Member (Non-Certified Institution)	7	7
Jurisdictional Representative		3
Manager/Director/Institution (Certified Institution)	11	11
Manager/Director/Institution (Non-Certified Institution)	4	13
Researcher/Sponsor	20	25
Total	**52**	**81**