Australian Government
National Health and Medical Research Council

NHMRC

Certification Handbook

National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research

November 2012

WORKING TO BUILD A HEALTHY AUSTRALIA

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National Health and
Medical Research Council

Certification Handbook

National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research (November 2012)

Information for Institutions and
Human Research Ethics Committees

Contents

Section 1 – Introduction to the National Certification Scheme

Outline of this section

This section introduces the National Certification Scheme.

- 1.1 provides a background on the development of the Certification Scheme.
- 1.2 provides advice on who should use this handbook.
- 1.3 – 1.5 includes definitions of abbreviations, useful references and definitions of important terms.
- 1.6 identifies useful contacts.

1.1 Background

The Harmonisation of Multi-centre Ethical Review (HoMER) initiative was established in 2006 to develop an approach to minimise duplication of the ethical and scientific review of human research in accordance with Chapter 5.3, Minimising Duplication of Ethical Review, of the *National Statement on Ethical Conduct in Human Research* (2007) (the *National Statement*). The tools developed under the HoMER initiative, including the National Certification Scheme, support the National Approach to Single Ethical Review (the National Approach).

Certification is one means to build confidence in the use of a single ethical review by all institutions participating in multi-centre research. Certification provides assurance to institutions, NHMRC and other research or health organisations that the policies, processes and procedures of an institution and its Human Research Ethics Committee (HREC) comply with an agreed set of national criteria for the conduct of an ethical review of multi-centre human research.

The aim of certification is to provide an independent validation of the rigour of the institutional ethical review processes for multi-centre[1] research. Institutions should have confidence that the HREC that reviews research using certified review processes is appropriately constituted, and that its institution's polices, processes and procedures meet an agreed national set of criteria.

Before certification is granted, the institutional ethical review processes undergo an independent assessment conducted by the Certifying Body. The NHMRC is currently the Certifying Body.

Certification begins with the institution carrying out a self-assessment of its ethical review processes and supporting structures. This is followed by a desktop assessment by the NHMRC before an on-site visit to verify institutional claims and practices.

1 In this document, 'multi-centre' includes research conducted through the collaboration of at least two unique institutions that may be situated in more than one state or territory or within a single jurisdiction. It does not refer to research being conducted at several sites or locations of a single institution.

Certification is dependent on a satisfactory demonstration of institutional compliance with specified criteria (see Appendix 9.1) which, in part, are based on the *National Statement* or any document that complements, supplements or succeeds it.

The National Certification Scheme will continue to evolve over time. Institutions should check the Human Research Ethics Portal (HREP) (**http://hrep.nhmrc.gov.au/**) to ensure they are using the latest guidance documents when preparing for certification.

1.2 Who should use this Handbook?

This handbook outlines the requirements and procedures for the certification of the processes used for and supporting the ethical review of multi-centre human research. The *National Statement* (2007) is the primary reference used for the development of certification assessment criteria.

The handbook should be used by institutions, and the research governance officers supporting HRECs, as a guide to applying for certification under the National Certification Scheme. It sets out the expectations and processes of the NHMRC in considering the institution's nomination. Institutions that have been certified by the NHMRC should also refer to this document as it details important information on on-going reporting requirements, complaints handling processes, suspension or revocation of certification and applying for a renewal of certification.

As users of the National Approach, researchers; research administration officers; and HREC Chairs and members may also find this information of assistance.

1.3 Relationship of the National Certification Scheme to State and Territory systems

Nothing in the National Approach, including this document, overrides National, State or Territory administrative or legislative requirements. For example, researchers may still need to comply with local allocation systems for coordinating ethics applications; institutions may be obliged to implement sector specific IT platforms or information sharing arrangements and local and national laws will continue to apply to human research.

For an indicative list of relevant State, Territory and Federal law relating to human research please refer to the Human Research Ethics Portal: **http://hrep.nhmrc.gov.au**

1.4 Abbreviations

ARC	Australian Research Council
AVCC	Australian Vice-Chancellors' Committee (now Universities Australia)
CEO	Chief Executive Officer
COI	Conflict of Interest
HREC	Human Research Ethics Committee
HREP	Human Research Ethics Portal (**http://hrep.nhmrc.gov.au**)
ISO	International Standards Organization
KPI	Key Performance Indicator
NHMRC	National Health and Medical Research Council
ONHMRC	Office of the National Health and Medical Research Council
SOP	Standard Operating Procedure
TGA	Therapeutic Goods Administration
ToR	Terms of Reference

A full list of terms and abbreviations used in the National Approach are on the HREP (**http://hrep.nhmrc.gov.au/national-approach/glossary**)

1.5 Useful references

Please visit **http://hrep.nhmrc.gov.au** for more information

1. NHMRC – *National, State and Territory Legislative Framework for ethical review of multi-centre research* (2012) available at **http://hrep.nhmrc.gov.au**
2. NHMRC – *Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research* (2012) available at **http://hrep.nhmrc.gov.au**
3. NHMRC – *Research Governance Handbook: Guidance for the national approach to single ethical review* (2011) available at **http://hrep.nhmrc.gov.au**
4. NHMRC – *Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics* (2006)
5. NHMRC – *Values and Ethics. Guidelines for ethical conduct in Aboriginal and Torres Strait Islander Health Research* (2004)
6. NHMRC/ARC/AVCC *National Statement on Ethical Conduct in Human Research* (2007) (*National Statement*)
7. NHMRC/ARC/Universities Australia – *Australian Code for the Responsible Conduct of Research* (2007)
8. TGA – *Notes for Guidance on Good Clinical Practice (CPMP/ICH/135/95) Annotated with TGA comments* (July 2000)

1.6 Definition of important terms

Assessor – An individual who considers information provided by the institution and/or observations of institutional practice to make a recommendation to the NHMRC on conformance to an agreed standard. An assessor may also gather information through interviews with key personnel and stakeholders. See Section 8.2 for further information.

Certification – The determination that a process conforms to the standard or criteria determined by the NHMRC.

Certifying Body (NHMRC) – For the purposes of the National Certification Scheme, the NHMRC is the entity with responsibility for deciding, on the basis of the assessment team's recommendations, to issue (or not to issue) a certificate of conformance to the agreed standard or criteria (where appropriate).

Desktop assessment – An off-site assessment conducted by an assessor that verifies information provided by an institution satisfies the requirements of the nomination process.

Institution – The entity that nominates its processes for ethical review for assessment against criterion contained in the National Certification Scheme (see Appendix 9.1).

Monitoring – 'The process of verifying that the conduct of research conforms to the approved proposal.'[2] For multi-centre projects where there has been a single ethical review adopted by all participating institutions, monitoring is a shared responsibility between participating institutions (through their research governance and administrative functions), the researcher at each centre and/or site and the relevant study team and the HREC that reviewed the research protocol. A study sponsor may also undertake monitoring.

On-site assessment – An assessment occurring on the premises of the nominating institution.

Self-assessment – The first step towards certification (see Appendix 9.1) where the institution reviews and confirms its readiness for assessment.

2 NHMRC/ARC/AVVC *National Statement on Ethical Conduct in Human Research* (2007) Chapter 5.5 *Monitoring Approved Research.*

1.7 Useful contacts

For further information on the National Approach and the National Certification Scheme please visit the NHMRC's Human Research Ethics Portal: **http://hrep.nhmrc.gov.au**

If you have any questions on the National Certification Scheme, including the status of your institution's nomination, please contact:

Program Assurance and Research Integrity Section
National Health and Medical Research Council

Phone: (+61 2) 6217 9213
Email: **hrep@nhmrc.gov.au**
Fax: (+61 2) 6217 9175

Section 2 – Applying for certification

Outline of this section

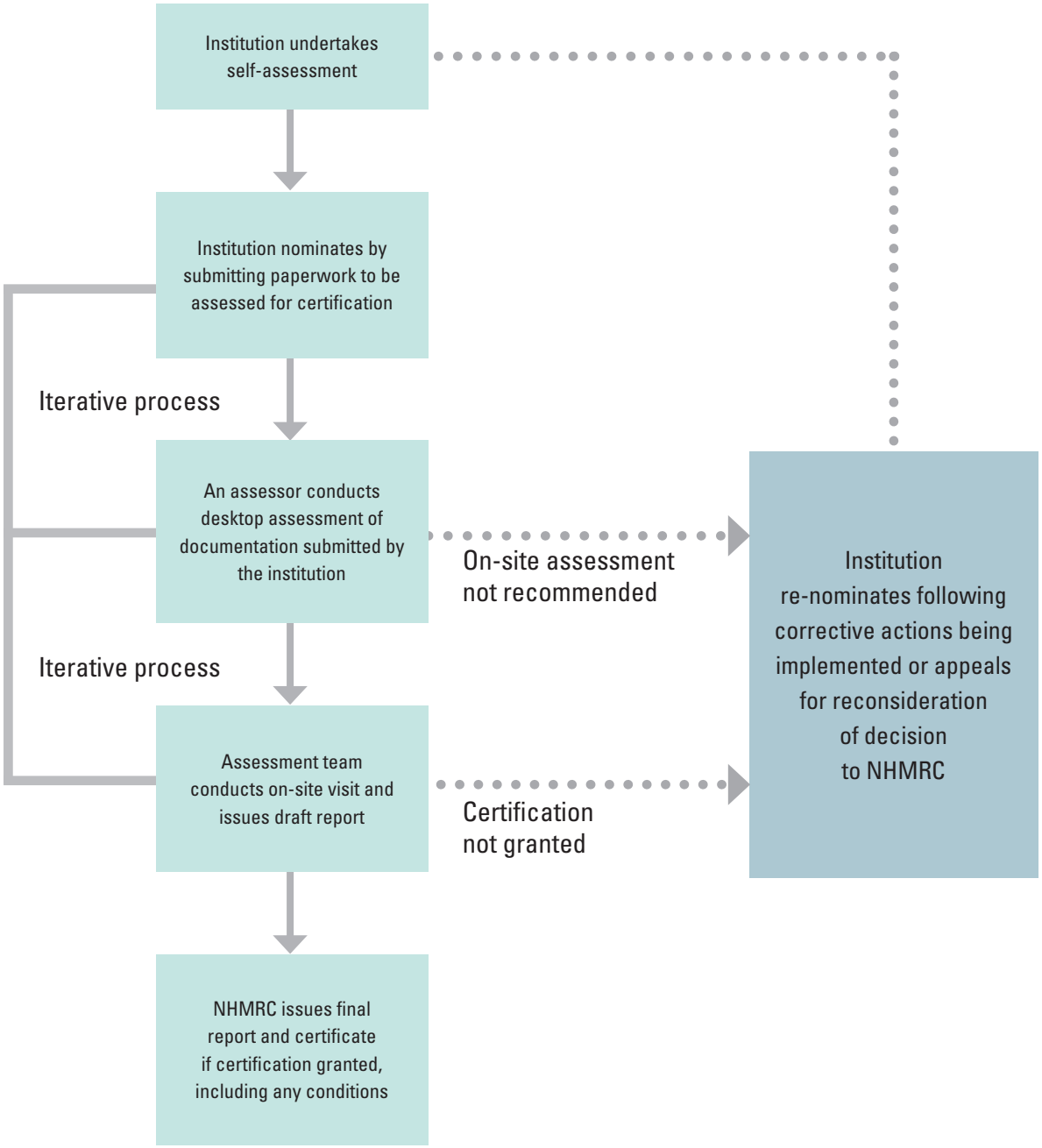
This section sets out important information for institutions preparing to nominate for certification under the National Certification Scheme.

- 2.1 outlines the nomination process, including the dates for submitting mandatory paperwork.
- 2.2 details the categories of research an institution can apply for certification in under the National Certification Scheme, including a brief definition of each category.

Achieving certification can be expected to take between three (3) to six (6) months. The process begins with the opening of a 'nomination round', during which time an institution completes a self-assessment of its ethical review processes and submits the self-assessment form, a nomination form and all supporting documentation to the NHMRC. This is followed by a desktop assessment of the material provided and usually an on-site visit by the assessment team (where deemed appropriate).

These steps are set out in Figure 1 (see over page).

Figure 1: Certification flowchart



2.1 Nomination rounds and the Self-Assessment Form

Information on opening and closing dates for nomination can be found on the HREP (**http://hrep.nhmrc.gov.au/certification/nomination-certification**).

Institutions that choose to nominate their processes for certification will need to allow sufficient time to complete the self-assessment form (at Appendix 9.2). The self-assessment form is more than the first step in the certification process; rather it leads the institution through the requirements for certification and provides a valuable opportunity for the institution to review its ethical review processes and determine whether they meet the requirements of the *National Statement* and the National Certification Scheme. Only when the institution is satisfied that it can demonstrate that it meets the requirements of certification should it complete and submit the self-assessment form to the NHMRC.

The institution will also complete the nomination form (at Appendix 9.3). The completed nomination and self-assessment forms, along with copies of documents in support of the institution's claims, are then forwarded to the NHMRC. Supporting documents will assist the assessors in determining the level of maturity[3] of the institutional arrangements supporting ethical review.

2.1.1 What documents must the institution submit as part of its nomination?

Mandatory documents are listed in the self-assessment form. These ***must*** be provided to the NHMRC, although an institution may also wish to provide additional documents and/or templates that would assist the assessors.

Examples of mandatory documents include:

- Copy of duty statement or position description form for administrative officer(s) supporting ethical review process
- Terms of Reference (ToRs) for the HREC and the associated subcommittees
- Standard Operating Procedures (SOPs) related to ethical review process
- Templates of documents used by HREC to communicate with researchers
- Copy of template letter of appointment for HREC members
- Institutional policies related to ethical review
- Any annual report(s) on ethical review processes provided to an institution's governance officers or board.

All forms and supporting documents should be submitted to the NHMRC in an electronic format (**.doc or .pdf format**). Where the institution does not have a document in electronic format or institutional policy prohibits its transfer to a third party, then a clear citation of the document must be provided in their self-assessment form and the document made available for review in the event of an on-site assessment.

Many documents that may support institutional claims for processes of ethical review of single centre research will be relevant to ethical review of multi-centre research. Institutions may submit these documents as evidence of claims, rather than revising them to explicitly refer to multi-centre research.

The Head of Institution, not the Chair of the HREC, nominates the institution's process for ethical review of multi-centre research for certification. The Chair of the institutional HREC signs the nomination form to indicate their awareness of the nomination.

The NHMRC may refuse to accept an institution's nomination for certification if it fails to provide ***all*** mandatory documentation, including the signed nomination form, before the close of a nomination round.

3 In this document, 'level of maturity' denotes the level of formality of the institutional arrangements for ethical review relative to the size and complexity of the institution itself. The level of maturity of institutional arrangements *in itself* will not preclude consideration for certification but may help inform an institution on how its approach compares with the wider field of applicants.

2.2 Categories of research recognised under the National Certification Scheme

When submitting a nomination for certification, institutions are required to indicate the categories of research and the targeted populations for which they wish to be certified. Certification under the National Certification Scheme is open to all organisations that provide ethical review of human research.

Certification is for specific research categories, and an institution will be expected to demonstrate that its HREC has the appropriate level of experience reviewing research proposals in each nominated category. Where an institution is seeking to broaden the range of research its HREC reviews it will need to ensure that, prior to nomination, it has access to expert reviewers to ensure the ethical review outcomes of its HREC meets the standard expected under the *National Statement*.[4] As research can and often does – overlap disciplines, institutions should consider whether they need to apply for additional categories of research, noting that they would still be required to demonstrate the appropriate level of HREC expertise.

The following human research categories are available for certification under the National Certification Scheme. An institution may apply for certification in one or more categories and in relation to specific vulnerable populations.

Justice health	Mental health
Population health and /or Public health	Qualitative research
Clinical trials[5]	Clinical interventional research other than Clinical trials
Other health and medical research	Other human research (not health and medical)

Institutions are also required to elect if their nomination relates to research involving any of the following categories of vulnerable participants:

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 in dependent or unequal relationships
People who may be involved in illegal activities	People with a cognitive impairment, an intellectual disability, or a mental illness

For some categories or targeted populations (e.g. children and young people) an institution may be required to undergo a specialist assessor review of the relevant ethical review processes at either the on-site visit or via teleconference.

4 For example, an institution's HREC may have significant past experience reviewing justice health research proposals but expects it will, in the future, also review mental health research proposals. In this case, the institution must demonstrate that it has sufficient processes in place to assure the assessors of its competency in reviewing the mental health category before certification will be granted.

5 Certification under "Clinical Trials" requires an institution to also nominate for trial type (drug, device or surgery) and trial phase(s) (0, I, II, III, IV).

2.2.1 Definition of categories of research

Under the certification scheme, categories of research have been determined as follows:

Justice health[6]

Justice health research is concerned with high risk populations who are directly under the control of criminal and juvenile justice systems or otherwise limited in freedom against their will because they are accused, charged with, held on remand, or in the community under license or bail for an offence or breach of an Australian law.

Justice health research may also involve participants indirectly affected by incarceration, arrest or other justice system contact, for example, corrective service personnel; young people with one or more parents in prison; members of a community with a disproportionately high incidence of contact with the justice system; or victims of crime and their families.

Research in this field may include direct intervention or the evaluation and analysis of: therapeutic or non-therapeutic interventions, health outcomes for participants currently residing in or recently released from prison, or the availability and effectiveness of justice health services brokered by corrective or justice actors.

Mental health

Mental health is a state of wellbeing in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community.

Mental health is the embodiment of social, emotional and spiritual wellbeing. Mental health provides individuals with the vitality necessary for active living, to achieve goals and to interact with one another in ways that are respectful and just.[7]

Mental health research may involve research into the causes and treatment of mental illness or mental disorder. Mental health research may include therapeutic and non-therapeutic interventions. Mental health research also includes research involving the disciplined inquiry into mental health promotion (including the evaluation of mental health policies or initiatives).[8]

Population and/or Public Health

The purpose of research within this category is to develop or contribute to generalisable knowledge to improve public health practice. Intended benefits of a project can include study participants, but always extend beyond the study participants, usually to society; and data collected regularly exceed requirements for care of the study participants or extend beyond the scope of the activity.

Research activities include the collection and analysis of qualitative and quantitative survey data, the analysis of administrative datasets, economic evaluation of health care interventions, health care financing priority, evaluation of health services and health policy, studies and knowledge translation. It includes population-level and health-system research, but not clinical or biomedical research.

Qualitative research

Qualitative research involves disciplined inquiry that examines people's lives, experiences and behaviours, and the stories and meanings individuals ascribe to them. It can also investigate organisational functioning, relationships between individuals and groups, and social environments.

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6 This definition of Justice Health research draws on the language provided by The Cochrane Collaboration at **http://justicehealth.cochrane.org/** (accessed 23 November 2011).

7 VicHealth (2005) *A plan for action 2005–2007: promoting mental health and wellbeing*, Victorian Health Promotion Foundation, Carlton South.

8 World Health Organisation (2001) *World health report: mental health: new understanding, new hope,* Geneva.

This approach to research can involve the studied use and collection of a variety of empirical materials such as case studies, personal experience, life stories, interviews, observations, and cultural texts. It may bring new insights into the experiences of individuals, groups or communities, or into issues such as environmental change, public policies and planning. Qualitative research may also have quantitative elements or aspects (National Statement 3.1).

This category is not limited to qualitative health and/or medical research, and includes all qualitative human research.

Clinical Trials

'A research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.'[9]

A clinical trial is the name commonly given to research in which a therapeutic, preventive or diagnostic intervention is tested in a particular, systematic way. The terms 'clinical trial' and 'clinical research' are sometimes used interchangeably but frequently 'clinical trial' is used to refer to the systematic testing of a drug or a medical device (i.e. a 'therapeutic good'), which is subject to the *Therapeutic Goods Act 1989*. Sometimes certain complementary or alternative medicines are considered therapeutic goods for the purposes of the Act.

PHASES OF INVESTIGATION

Phase 0

Includes exploratory, first-in-human trials. Phase 0, as a category for clinical trials, has become increasingly common and described research studies also referred to as pilot studies or exploratory investigational drug (IND) studies.

Phase 0 trials are also known as human micro-dosing studies and are designed to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was anticipated from preclinical studies. Exploratory trials are conducted before traditional dose escalation and safety studies and gives no data on safety or efficacy, being by definition a dose too low to cause any therapeutic effect.

Phase I

Includes initial study to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients. Trials are often dose ranging/escalating trials, which are done to determine the maximum dose of a new medication that can be safely given to a patient.

Phase II

Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups (20-300) and are designed to assess how well the drug works, as well as to continue Phase I safety assessments in a larger group of volunteers and patients. When the development process for a new drug fails, this usually occurs during Phase II trials when the drug is discovered not to work as planned, or to have toxic effects.

Some trials combine Phase I and Phase II, and test both efficacy and toxicity.

Phase III

Phase III trials include expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of a new drug/medication or intervention, including possible adverse reactions. It is also to provide an adequate basis for physician labelling.

Phase IV

Post-marketing study sometimes required by a drug safety agency (e.g. the TGA or US FDA). Phase IV trials are done to monitor the toxicity, risks, utility, benefits and optimal use after the efficacy of the drug/medication or intervention has been proven.

9 International Clinical Trials Registry Program, World Health Organization accessible at **http://www.who.int/ictrp/en** (accessed 28 November 2011).

INTERVENTION TYPE

Drug

Clinical trials involving drugs are designed to study and assess the safety and effect(s) of one or more chemical or biological agents including vaccines.

Surgery and other procedural interventions

A clinical trial designed to assess the effect(s) of one or more manual or operative surgical techniques, whether it is in the field of cosmetic, elective, experimental, plastic, or replacement surgery (which are performed to diagnose, treat, or prevent disease or other abnormal conditions).

Devices

Clinical trials designed to evaluate the use of any physical item used in medical treatment whether it is an instrument, piece of equipment, machine, apparatus, appliance, material or other article, with the intention of preventing, diagnosing, treating, and curing a disease or condition and whether it is used alone or in combination. Examples include: artificial limbs, contact lenses, ventilators, catheters, implants, condoms or vibration therapy machines.

Other

Studies that do not fall under the broad definitions of drug, surgical, or device trials. Examples include interventions such as exercise, physiotherapy, cognitive therapy, special diets, herbal medicines, web-based treatments, motivational classes, music therapy, and stem cell interventions.

Clinical Interventional Research other than clinical trials

Interventional research involving human participants in health and illness done in response to a clinical research question. The aim of such research is to inform clinical practice through the application of patho-physiological, population-based, behavioural or qualitative research methods.

Other health and medical research*

Please nominate this category if your institution seeks certification for the ethical review of multi-centre health and medical research, which does not fall into one of the above categories. Examples of health and medical research which should be specified here may include: Human Movement and Sports Science; Nutrition and Dietetics; Genetics; and Drug and Alcohol.

Please refer to the NHMRC's *Fields of Research Guidelines* for further information.

Other human research (not health and medical research)*

Please nominate this category if your institution seeks certification for the ethical review of multi-centre human research that is not health and medical research. In specifying the subgroup of research for which your institution is seeking certification please refer to the Fields of Research set out at Chapter 3 of the Australian Bureau of Statistics publication: *1297.0 — Australian and New Zealand Standard Research Classification* (ANZSRC), 2008.

Examples in this category include: Education (including Language, Communication and Culture); Philosophy and Religious Studies; Psychology and Cognitive Sciences; and Studies in Human Society (including law and legal studies).

* If your institution nominates this category, the NHMRC will contact you to discuss the scope of the category prior to an on-site visit occurring.

Section 3 – Desktop assessment and on-site assessment of institutional processes for ethical review

Outline of this section

This section explains how the NHMRC assesses the ethical review processes of an institution.

- 3.1 – 3.1.1 provide an overview of the internal assessment process.
- 3.2 outlines the desktop assessment process, which leads to a desktop assessor's recommendation that an institution proceed to an on-site assessment.
- 3.3 details the on-site assessment process, including a general overview of the day, and the post-visit steps required before a formal recommendation is made to the NHMRC to certify the institutional processes for ethical review.
- 3.4 – 3.6 sets out the process for finalising the report and recommendation to certify, including the timeframe for each stage following the on-site visit.

3.1 Process for granting and maintaining certification

The assessment of institutional processes for ethical review of multi-centre human research against agreed national standards (Appendix 9.1) will consider an institution's policies, processes, procedures and practices. This work is conducted by assessors who have demonstrated to the NHMRC that they are suitably qualified to undertake an assessment and have no Conflict of Interest (COI) that prevents them from assessing a particular institution. Further information on assessors is set out in Section 8.2.

3.1.1 Nomination and Self-Assessment

An overview of the certification process is provided above in Figure 1 in Section 2. Information on the nomination process, including the self-assessment and nomination forms and categories of research can be found in sections 2.1 – 2.2.

3.2 The desktop assessment

To begin the assessment for certification, an institution will submit the self-assessment, nomination and declaration forms and copies of required documents to the NHMRC. These documents collectively represent the institution's claim that its processes for the ethical review of multi-centre research meet the agreed national standards. Following the receipt of these documents, the NHMRC will conduct a desktop assessment of the paperwork.

An assessor conducts a desktop assessment and verifies that the institution has addressed all matters in the self-assessment form. The institution will be given the opportunity to respond to any matters of concern identified[10] in the assessment and may be required to submit additional supporting information.

Following the consideration of additional material or information provided by the institution, the desktop assessor will prepare a recommendation to the decision maker, recommending either:

1. **The institution proceed to an on-site assessment**

   or

2. **The institution should not proceed to an on-site assessment and the Head of the Institution is informed of the outcome of the desktop assessment.**

An institution may proceed to an on-site assessment even if the NHMRC identifies deviations from the *National Statement* or certification criteria. However, an institution is unlikely to be recommended for an on-site assessment if these deviations are such that there is no reasonable prospect of the institution achieving compliance with the *National Statement* or certification criteria within a six month period.

The decision of the NHMRC will be provided in writing to the Head of the Institution or their delegate following desktop assessment (see Section 8.1 – *Decisions of the NHMRC*).

3.3 On-site assessment

In the on-site assessment, the NHMRC confirms the institution's claims in relation to its capacity to carry out ethical review of multi-centre research proposals.

Prior to the on-site assessment, the NHMRC will notify the institutional contact officer of the proposed assessment team and schedule for the day. The institution will have an opportunity to request a change to the assessment team on the grounds of an actual or potential COI. Perceived conflicts of interest will be resolved by the NHMRC, in consultation with the relevant assessor.

While the NHMRC will take all possible steps to accommodate the needs of the institution, late changes to the assessment team may result in changes to the date for the on-site assessment.

The on-site assessment will follow a uniform approach for all nominating institutions. However, the complexity of the on-site assessment (i.e. the time required for the assessment and the depth of inquiry) may vary according to the volume and nature of the ethical review of multi-centre research carried out by the institution's HREC or the particular categories of research in which the institution is seeking certification. Please see **Figure 2 (page 15)** for further information.

The on-site visit begins and concludes with a short meeting between the on-site assessment team, the Head of Institution or their delegate and the relevant institutional staff to discuss the plan for the visit and the preliminary findings of the visit respectively. The Chair of the HREC may be present at the invitation of the Head of the Institution.

During the visit, the assessors will seek to verify conformance with the *National Statement* and certification criteria. The assessor will also examine the consistency between the institution's documented processes (e.g. SOPs and ToRs) and actual practice. This may include accessing relevant institutional administrative records, observing HREC deliberations or interviewing HREC members and institutional administrative staff.

10 This process results in the institution implementing 'corrective actions' to correct perceived deviations from the requirements for certification. Alternatively, the NHMRC may request additional evidence (i.e. supporting documentation) to clarify a point of confusion.

3.4 Progressing to a recommendation to certify

Within 15 business days of the on-site assessment, the assessment team will prepare and provide the institution with a copy of their draft recommendations. The institution will have an opportunity to respond to the recommendations and correct any errors of fact.

During this period the institution may begin to implement any changes in processes or documentation recommended by the assessment team during the on-site visit. However, unless the changes are minor in nature (e.g. amending typographical errors, or clarifying inconsistencies across documents) the draft report will reflect the state of affairs as of the day of the on-site assessment.

The assessment team will then finalise the report and will make a formal recommendation to the decision-maker to grant certification or not grant certification for the institution. Should the NHMRC decide not to grant certification, reasons for the decision will be provided in writing to the Head of the Institution.

In the event that certification is not granted, assessors will continue to work with the institution in order to address the deficiencies outlined in the final assessment report. Institutions will need to address the deficiencies within 12 months of being issued the final assessment report in order for certification to be considered under the current nomination. If an institution is unable to address the deficiencies, 12 months from receipt of the final assessment report, the institution may be required to submit a new nomination.

Subject to the number of institutions applying for certification in any one round, the following timeframes will apply to finalising a recommendation to certify:

Activity	Timeframe	Responsible Party
Preparation of the draft assessment report	15 business days after the on-site assessment	Assessment team
Review of draft assessment report and correction of errors of fact.	15 business days from receipt of the draft assessment report	Institution. Comments to be provided to NHMRC
Approval of draft report	10 business days from receipt of the institution's comments on the draft report	Assessment team Institution to confirm changes
Finalisation of report, including recommendation to grant or not grant certification	10 business days from receipt of email from institution confirming the necessary corrections have been made	Assessment team
Decision to certify or refuse certification of institutional ethical review processes	30 days after finalisation of the assessment report	NHMRC decision-maker

3.5 Granting certification

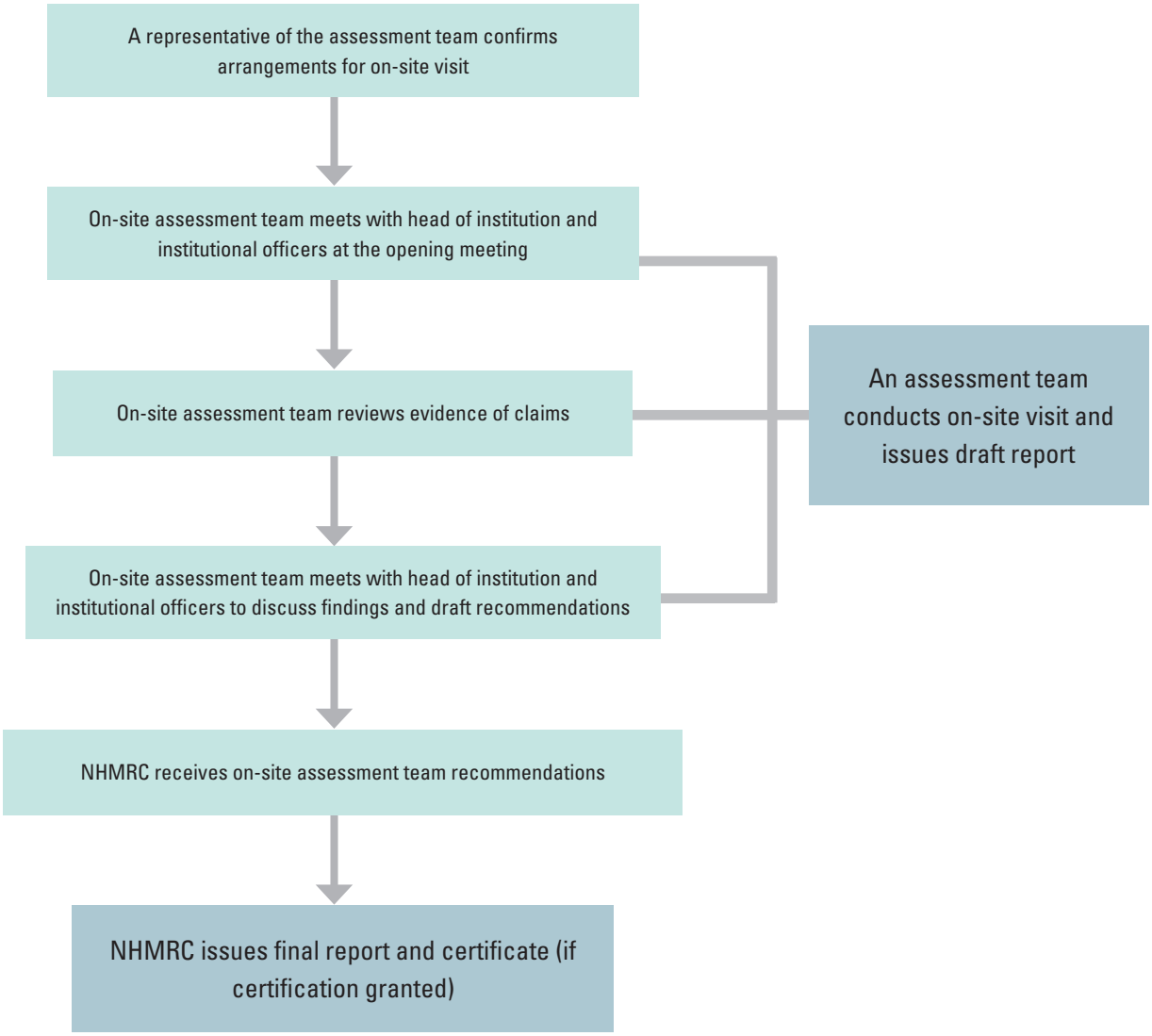
Where the NHMRC decides to certify the institution's ethical review processes, the institution will receive a signed certificate stating its period of currency.[11] The certificate is accompanied by a report recommending, as needed, areas where the institution may improve its practice over the initial period of certification. For further information on how these recommendations will be monitored see Section 6 – *Renewal of Certification.*

Alternatively, the NHMRC may decide not to certify the institution's ethical review processes. In this case, the institution will receive a letter outlining areas where the institution must make changes before a new nomination for certification will be considered.

11 For most institutions, the period of certification will be a minimum of two years before review. This period could vary depending on the categories of research nominated by the institution, changes in institutional arrangements reported by the institution to the NHMRC or in response to receipt of complaints about the conduct of an institution's certified ethical review processes.

Figure 2 below depicts in more detail, steps related to the on-site visit and the decision to grant, or otherwise, certification.

Figure 2: Steps related to the on-site visit and the decision to grant



Section 4 – Reporting obligations for certified institutions

Outline of this section

This section sets out the reporting obligations for certified institutions. Reporting obligations apply to all institutions that are certified under the National Certification Scheme.

- 4.1- 4.1.4 details mandatory reporting obligations for all certified institutions.
- 4.2 outlines reporting requirements for certified institutions which will commence from 2012. A modified version of the annual report was distributed to institutions for the 2011 calendar year. Institutions will be required to provide information on the timeliness, quality and reduced duplication of ethical review.
- 4.2 also sets out the definition of 'stop-clock'.

4.1 Reporting requirements for certified institutions

Institutions whose processes for ethical review of multi-centre human research have been certified (certified institutions) are required to submit annual reports to the NHMRC as part of the ongoing monitoring and reporting requirements, unless more frequent reporting has been included as a condition of their certification. Certified institutions will also have separate reporting obligations as a condition of the registration of their HREC with the NHMRC.

Failure to comply with any reporting requirements will be considered grounds for suspension or revocation of certification – see Section 5 – *Suspension and Revocation of Certification*.

4.1.1 Annual reporting under the National Certification Scheme

Certified institutions are required to submit an annual report via the HREP to the NHMRC. Completed forms should be sent to **hrep@nhmrc.gov.au.**

4.1.2 Proactive reporting to the NHMRC

As a condition of certification, certified institutions are required to promptly notify the NHMRC when there has been a significant change to their certified ethical review processes and/or HREC membership. Notification is expected if, for example, the institution implemented a new application form for ethical review, abolished a scientific or low risk subcommittee which previously provided advice to its HREC or altered its SOPs or ToRs in relation to quorum and minimum membership of the HREC.

4.1.3 Other reporting

Institutions may also be requested to provide additional evidence as a condition of certification (for example, evidence that the institution has implemented improvements recommended by the NHMRC). These requirements are determined on a case-by-case basis by the NHMRC.

Please note that the NHMRC also requires a separate annual report from all HRECs registered with NHMRC.

4.2 Reporting on quality, timeliness and reduced duplication of ethical review in line with the Key Performance Indicators (KPIs)

Key Performance Indicators (KPIs) have been developed to assist in measuring the effectiveness of the National Approach. These KPIs fall into the broad categories of quality, timeliness and reduced duplication of ethical review. Compliance with the reporting requirements is mandatory for all certified institutions.

The KPIs and the way in which they are proposed to be measured are outlined below.

Quality

- Adoption of standardised ethical and scientific review processes and procedures.
  - Measured by the number of institutions with certified ethical review processes and the number of institutions maintaining certification (NHMRC to collect).
- Number of complaints about the national approach to single ethical review.
  - Measured by the number of complaints received by the NHMRC.

Timeliness

- Adoption of a sixty (60) day timeframe for ethics review.*
  - Measured by the proportion of reviews that meet the sixty (60) calendar day timeframe.
- Time taken for ethical and scientific review carried out by institutions with certified ethical review processes as reported in the NHMRC Annual Report.
  - Measured by self-reporting by certified institutions.
  - Measured by category of research.
  - Measured by sector of institutions.

Reduced duplication

- Measured by the number of multi-centre projects approved under the National Approach to Single Ethical Review (NHMRC to collect data through the Certified Institution Annual Report Form).
- Measured by the number of sites covered by the single ethical approval (by sites listed on NEAF).
- Measured by the number of reviews that were inter-jurisdictional and the number that were intra-jurisdictional (NHMRC to collect data through its Annual HREC Report form).

*Definition of sixty (60) calendar days for ethical review

In order to ensure consistency in reporting mechanisms, the definition below should be used by certified institutions when calculating sixty (60) calendar days for the purpose of reporting against the 'timeliness' KPI:

"Sixty (60) calendar days are allowed for the ethical review of an application. Where a valid application is received, the clock starts on the submission closing date for the HREC meeting at which an application will be reviewed. The clock stops when a request for further information or clarification is requested from the applicant. The clock recommences when the requested information or clarification has been received. The clock is stopped when the HREC formally notifies the applicant of the final decision."

Section 5 – Suspension and revocation of certification

Outline of this section

This section sets out the grounds for and consequences of suspending or revoking an institution's certification. It should be read in conjunction with the information at **Section 7.1** *Complaints Handling under the National Certification Scheme* and **Section 8.1** *General Principles for Decision Making under the National Certification Scheme*.

- 5.1 – 5.1.2 details the option available to theNHMRC to suspend an institution's certification, possible grounds for suspension and the consequences of a decision to suspend an institution's certification.
- 5.2 outlines an option for institutions to suspend their certification voluntarily.
- 5.3 and 5.3.1 discuss revocation of certification, including consequences on future nomination for certification and circumstances which may justify immediate revocation.

In making a determination to suspend or revoke certification, the NHMRC will take into account deficiencies in an institution's ethical review processes as which could give rise to risks to the physical and emotional welfare and ethical treatment of research participants and any real or potential risk to the reputation of the NHMRC and the National Certification Scheme.

5.1 Suspension of certification

Suspension of certification can be initiated by the NHMRC or the institution (see 5.2 below) and places a temporary restriction on an institution's certification, either in full or in part. A review of an institution's certification may occur in response to a complaint lodged with the NHMRC or on the initiative of the NHMRC.

Note: Under the National Certification Scheme, the NHMRC grants certification to an institution for their multi-centre ethical review processes. This is on the basis that an institution is ultimately responsible for the conduct of its HREC and research occurring on its premises. In the event that an HREC fails to meet their obligations to the NHMRC, the institution's status as a certified institution is subject to suspension and/or revocation.

In line with the decision-making principles set out in Section 8 below, an institution will be notified prior to any decision by the NHMRC.

An institution's certification might be suspended entirely which, for the period of its suspension, means that it is not a certified ethics review body for multi-centre research.

In addition, an institution's certification may be suspended for review in one or more of its nominated categories of research. In this case, the institution's HREC could still conduct single ethical review of multi-centre research in categories of research where processes and expertise are maintained.

5.1.1 Grounds for suspending certification

Grounds for suspending certification include:

- failure by the institution via its HREC to meet its reporting obligations to the NHMRC
- failure by the institution to ensure that the HREC maintains the appropriate level of specialist knowledge for any nominated research categories
- failure to appropriately monitor multi-centre research in accordance with any NHMRC guidelines on monitoring multi-centre research or other relevant national or local guidelines
- failure by the institution to maintain the appropriate level of insurance for its HREC
- repeated, unreasonable refusals by the certified institution to accept the ethics review of another certified institution
- an unreasonable refusal by the certified institution to undertake a review of an application for single ethical review of multi-centre research
- failure by the HREC or certified institution to comply with the requirements of the National Statement, the Code for the Responsible Conduct of Research (2007) or any other guidance document issued by the NHMRC relating to the ethical or responsible conduct of human research
- failure to provide requested information to the NHMRC for the purposes of assessing whether the institution continues to meet the assessment criteria
- accepting an application for single ethical review of multi-centre research in a suspended research category subject to a partial suspension
- accepting an application for single ethical review of multi-centre research during a period of voluntary suspension (See 5.2)
- representing that the institution is certified to review multi-centre research in a category of research for which it is not certified
- failure by the institution to accept a valid application for ethical review of a multi-centre human research project submitted on the NEAF
- engaging in conduct which otherwise places participants, researchers and the public at risk or jeopardises the reputation of the National Certification Scheme.

5.1.2 Consequences of suspension

A suspension, including reasons, will be recorded by the NHMRC and the register of certified bodies at **http://hrep.nhmrc.gov.au/certification/hrecs** will also be updated to reflect a full or partial suspension.

Based on the subsequent actions of the institution, the NHMRC may lift the suspension (in full or in part) or revoke the institution's certification. Once lifted, the institution can resume those activities that were restricted under the suspension.

5.2 Voluntary suspension of certification

Where a certified institution anticipates that it will not be able to meet the assessment criteria of the National Certification Scheme, it may request the NHMRC to temporarily suspend some or all of its obligations under the National Certification Scheme.

If accepted, the institution's certification will be held 'in abeyance' and will be eligible for reactivation upon request, following the NHMRC being assured that the Institution meets the requirements of the Certification Scheme. During a period of abeyance an institution will be unable to participate as a certified institution in the National Approach but its inability to meet the assessment criteria during this period will not lead to unilateral suspension or revocation of its certificate of certification by the NHMRC.

After a period of three months an institution should advise the NHMRC of its intention to either resume participating in the National Approach or its decision to withdraw as a certified institution from the National Certification Scheme. If the institution is not yet sure whether it will continue to participate in the National Approach it should use this opportunity to discuss any outstanding issues with the NHMRC and request a further period of time in which to implement any necessary changes.

Failure to inform the NHMRC within the specific timeframe of the need for a further period of voluntary suspension may lead to the unilateral suspension and/or revocation of the institution's certification by the NHMRC.

5.3 Revocation of certification

Revocation of certification is initiated by the NHMRC and cancels the institution's certification status under the National Certification Scheme for the balance of the current period of certification. The NHMRC may revoke an institution's certification following a period of suspension (see 5.1 above) or immediately if the circumstances warrant.

Immediate revocation is likely if:

- the NHMRC forms a reasonable belief that deficiencies in an institution's ethical review processes could give rise to risks to the physical and emotional welfare and ethical treatment of research participants
- the institution has engaged in behaviour which, in the opinion of the NHMRC, constitutes a serious breach of the *National Statement* or other national, state or territory document which sets out standards for the ethical or responsible conduct of human research

  or
- the institution repeatedly refuses to comply with the reasonable requests of NHMRC to cease a practice in breach of an assessment criterion or to conform with an assessment criterion.

In line with the decision-making principles outlined in Section 8.1, decisions by the NHMRC to suspend or revoke certification will be provided in writing to the Head of Institution or their delegate.

5.3.1 Consequences of revocation of certification

An institution whose certification has been revoked may reapply for certification in the next round of nominations, however, the grounds or events which led to its certification being revoked will be considered by the NHMRC.

Section 6 – Renewal of certification

Outline of this section

This section sets out the processes for renewal of certification.

- 6.1 outlines the purpose of renewing certification
- 6.2 outlines the notification of expiry of nomination and calls for applications of renewal of certification.
- 6.3 details the timeframe and documents required for institutions wish to apply for renewal of certification.
- 6.4 outlines the desktop assessment process of an institutions application for renewal of certification.
- 6.5 outlines the requirements for an on-site assessment
- 6.6 details consequences for failure to renew certification.

6.1 Purpose

Institutions that have their multi-centre single ethical review processes certified under the National Certification Scheme will be granted certification for a period of up to three years during their initial period of certification. If an institution wishes to maintain its status as a certified institution, it will be required to submit an application for renewal of certification, prior to the current period of certification expiring (see Section 6.3). Renewing certification provides assurance to other research organisations, and to NHMRC that the policies, processes and procedures of an institution and its HREC continue to comply with the agreed set of national criteria for the conduct of an ethical review of multi-centre human research.

6.2 Notice of certification expiry and call for applications to renew certification

Nine months prior to the end of a period of certification, the NHMRC will request advice in writing from the Head of a certified institution as to whether the institution intends to seek renewal of certification.

The institution will be asked to respond to the NHMRC within three (3) months of the date of request to advise if the institution wishes to apply to renew their certification. If they do so intend, they will be required to submit evidence that supports their application for renewal of certification.

6.3 Applications for renewal of certification

In order to renew its certification, institutions will need to submit the Application for Renewal of Certification (Appendix 9.7), along with supporting documentation, to the NHMRC within the last nomination round preceding the expiration of an institution's period of certification. Supporting evidence will include:

- evidence that supports the institution's claims that has addressed any improvements identified in the assessment report on which current certification is based
- any mandatory documents, including SOPs and ToRs, that have been updated during the certification period
- the completed HREC Member Profile, HREC Sub-committee Profile and HREC Administrative Staff Profile
- endorsed HREC meeting minutes for the previous three (3) months and evidence of correspondence that relates to the decisions recorded in those minutes (this evidence can be provided in a de-identified form).

As part of the application for renewal of certification, a certified institution will be required to complete a revised self-assessment form (see Appendix 9.7).

6.4 Desktop assessment

Following receipt of a complete application the NHMRC will undertake a desktop assessment of the institution's application. The desktop assessment will verify that the institution has implemented the improvements required (if any) during the current period of certification and continues to meet the certification criteria. In the event that deficiencies in the documentation are found, the institution will be given the opportunity to respond. The NHMRC may request the institution provide additional documentation.

6.5 On-site visit

The need for an on-site visit will be informed by the institution's application for renewal of certification. Consideration will be given to whether or not there have been significant changes to HREC membership or practices; whether the institution has provided sufficient evidence to support its application for renewal; or if the institution wishes to amend the categories of research for which it is certified.

Institutions granted renewal of certification on the outcome of the desktop assessment alone, may be subject to a random on-site visit at any stage during the period of renewal of certification. Institutions should expect at least one on-site visit during any two successive periods of certification. This is intended to ensure an appropriate level of monitoring of institutions which would otherwise achieve renewal of certification on desktop assessment alone on successive occasions.

6.6 Granting certification

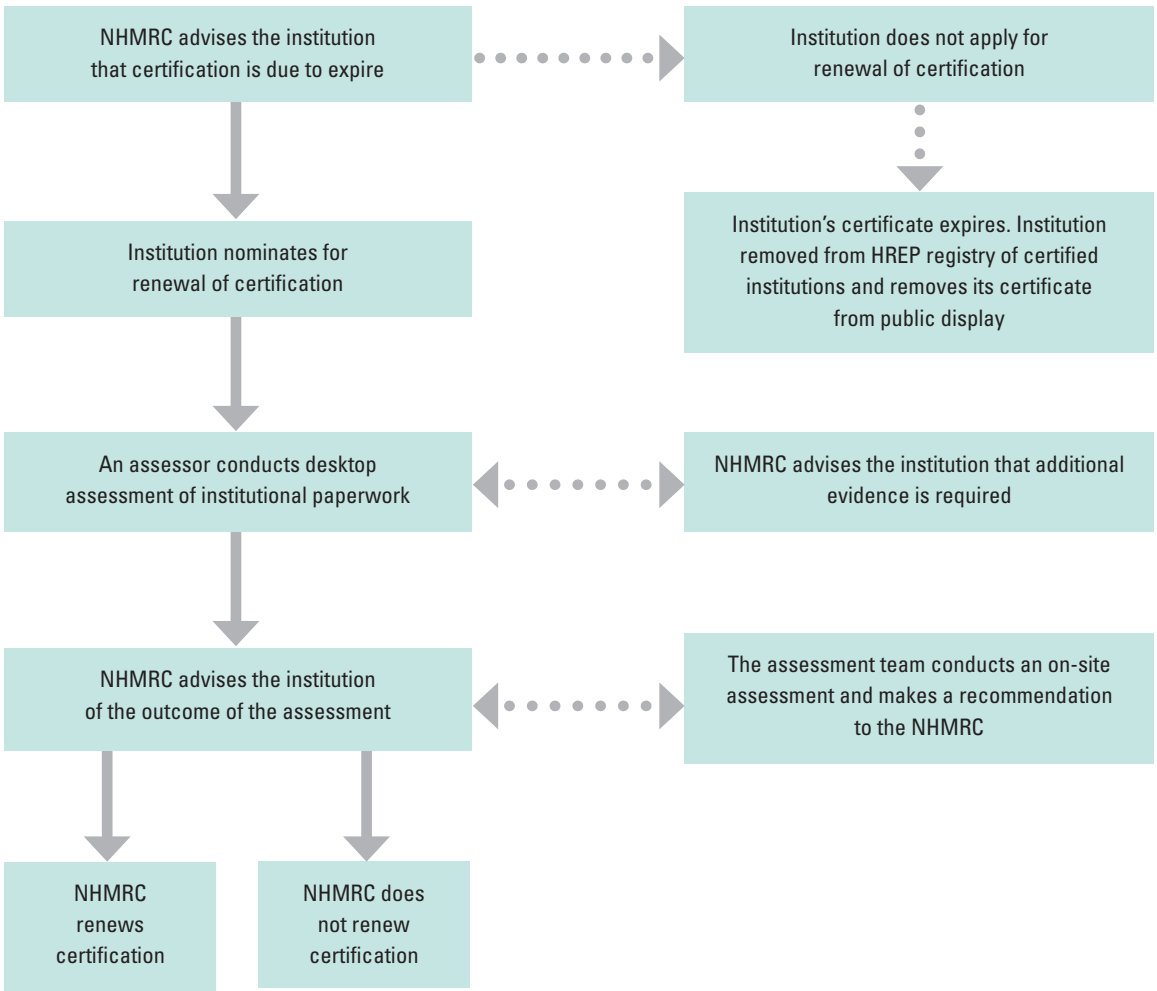
The NHMRC may determine a renewal period of certification that is greater than three (3) years, to a maximum of five (5) years. This decision is at the discretion of the NHMRC and will take into consideration matters identified in the initial and any subsequent periods of certification, as well as documentation provided as part of the application for renewal of certification.

6.7 Failure to renew certification

Failure of an institution to attain renewal of certification prior to the expiry of their current period of certification will mean that an institution will no longer be certified and will be removed from the register of certified institutions. The institution must also remove its certification certificate from public display and ensure that any correspondence and/or information on institutional practices are updated to remove references that it is a certified institution.

Should assessment of an application for renewal still be ongoing at the time of expiry of the current period of certification, the NHMRC may, at its discretion, temporarily extend or suspend certification pending the outcome of the assessment.

Figure 3 – Process for the renewal of certification



Section 7 – Complaints handling under the National Certification Scheme

Outline of this section

This section outlines complaints handling under the National Certification Scheme.

- 7.1 outlines mechanisms for complaints about the NHMRC.
- 7.2 outlines mechanisms for appeals against a decision made under the National Certification Scheme.
- 7.3 outlines processes for complaints about certified institutions.

In handling and resolving complaints and appeals the NHMRC will afford procedural fairness to institutions, recognising that fairness includes the timely resolution of a matter. As far as possible, the NHMRC will respect the interests of an individual or institution to have a matter resolved in confidence and consistently with the National Privacy Principles and Information Privacy Principles.

7.1 Appeals against a decision made under the National Certification Scheme

To appeal against a decision made under the National Certification Scheme, including a decision not to grant certification or proceed to an on-site visit, please contact the Director, Program Assurance and Research Integrity Section in the first instance.

RE: Certification Scheme – In-Confidence
Attention: The Director
Program Assurance and Research Integrity Section
National Health and Medical Research Council
GPO Box 1421
Canberra ACT 2601

Or contact the Director via: phone: (+61 2) 6217 9213

If the institution remains dissatisfied with the outcome of the internal review, it may request a review of decision by writing to the Chief Executive Officer (CEO) of the NHMRC, or delegate, with reasons for the request. Where a request for review is received, the CEO of the NHMRC or their delegate will conduct a review.

7.2 Complaints about certified institutions

Concerns about the **ethical review processes** of a certified institution should first be raised with the institution itself. Links to the website of certified institutions can be found at: **http://hrep.nhmrc.gov.au/certification/hrecs**. Complaints about the outcome of an ethical review will ***not*** be considered by the NHMRC.

If you remain dissatisfied with the response of the certified institution you lodge a complaint with the NHMRC by contacting the Director, Program Assurance and Research Integrity Section.

RE: Certification Scheme – In-Confidence
Attention: The Director
Program Assurance and Research Integrity Section
National Health and Medical Research Council
GPO Box 1421
Canberra ACT 2601

Or contact the Director via: phone: (+61 2) 6217 9213

7.3 Complaints about the NHMRC

The NHMRC Service Charter (**http://www.nhmrc.gov.au/_files_nhmrc/about/contract/complaints_servicecharter.pdf**) details our values and service level expectations. The receipt and investigation of complaints will be undertaken internally by the Office of the ONHMRC but may also come under the scrutiny of external agencies.

Internal review is appropriate for complaints about:

1. The actions or behaviour of staff of ONHMRC, including assessment team members – e.g. failing to disclose conflicts of interest;
2. The timeliness of NHMRC staff in responding to queries about the National Certification Scheme;
3. Significant deviations from the timeframes for Certification processes established by this Handbook.

To lodge a complaint about the actions of the NHMRC please refer to the NHMRC's *Policy on Complaints* **https://www.nhmrc.gov.au/_files_nhmrc/file/about/contact/policy_on_complaints.pdf**

and complete the online form at: **https://www.nhmrc.gov.au/about/contact-us/complaint-form** or

contact the NHMRC's Complaints Officer on (02) 6217 9333 or toll free on 1800 646726 to discuss your concern or seek assistance.

Section 8 – General information

Outline of this section

This section outlines decision making principles of the NHMRC.

- 8.1 outlines the decision making process.
- 8.2 outlines the appointment process for external assessors.
- 8.3 outlines management of conflicts of interest and confidentiality.

8.1 Decision making principles to be followed by the NHMRC

Decision making is an iterative process

Assessors and officers of the NHMRC will discuss areas of confusion, any need for additional information or materials and their preliminary conclusions with the institution.

Decision making will be fair, transparent and consistent

In making a decision to suspend or revoke certification, the NHMRC will take into account the deficiencies in an institution's ethical review processes which could give rise to risks to the physical and emotional welfare and ethical treatment of research participants and any real or potential risk to the reputation of the NHMRC and the National Certification Scheme.

An institution whose certification is under review must be afforded procedural fairness. This extends to:

- fully informing the institution, in writing, of the NHMRC's concerns over its processes
- providing access to a copy of the processes to be applied by a decision-maker in reviewing the institution's certification
- providing the institution with a reasonable opportunity to respond – in writing – to any adverse allegations, statements or findings on which a decision may be based
- ensuring all decisions are communicated in writing
- providing the institution with an opportunity to seek review of a decision made in the first instance.

A decision maker should presume that alleged deviations from certified ethical review processes occurred innocently unless shown otherwise. Likewise, a decision maker should not presume that a request to voluntarily suspend Certification under the National Certification Scheme (see Section 5.2) is due to a past failure to meet the assessment criteria.

The institution may request such a decision be reviewed (see Section 7.2).

8.2 Assessors

8.2.1 The role of assessors

Assessors are persons selected[12] by the NHMRC to conduct aspects of the certification process. The on-site visit will be carried out by a team of at least two assessors with one member taking on the role of lead assessor. The NHMRC may also use assessors to conduct the desktop assessment.

8.2.2 Appointment and qualifications of assessors

An assessment team will include a mix of external assessors and internal assessors. Internal assessors are staff of the NHMRC and will be appointed on the basis of expertise and availability. Internal assessors are required to declare all potential or real conflicts of interest.

External Assessors are appointed by the NHMRC to a formal Assessors' Panel. Currently, assessors are appointed by the NHMRC to a panel established under section 39 of the *National Health and Medical Research Council Act 1992*. From this panel, assessors are selected by the NHMRC to attend an on-site assessment visit and to review the material submitted for desktop assessment.

External assessors are drawn from:

- past and present researchers
- present and past HREC Chairs and members
- present and past institutional administrative officers (e.g. involved in research governance and/or research ethics administration)

All assessors are expected to have knowledge of and experience in applying the *National Statement* to ethical review processes and, on appointment, are required to complete an online training module and attend at least two on-site visits as a co-assessor before being able to lead an assessment team.

This condition may be waived in light of the member's past experience at the absolute discretion of the NHMRC.

Assessors may be eligible for remuneration as determined by the Remuneration Tribunal and for reimbursement for travel and accommodation costs.

8.3 Managing conflicts of interest and confidentiality

Assessors will not be a member or administration officer of the HREC or institution whose process for ethical review of multi-centre research is being assessed, or a researcher involved with, or intending to be involved with research reviewed by that HREC or institution.

A potential assessor must declare any financial conflicts of interest, the appearance of a financial COI, impropriety, or the appearance of impairment of their objectivity to the NHMRC via completion and submission of an Assessor Conflict of Interest Declaration and a Confidentiality Agreement (at Appendix 9.5). The potential for a COI resulting from a jurisdictional relationship between a potential assessor and an institution, i.e. current or previous employment in the same Area Health Service, should also be declared.

The same form will bind the assessor from not making public any confidential information acquired in the performance of their duties without the written approval of the Head of the Institution.

The institution must also consider and manage potential conflicts of interest for individuals involved in the certification process.

12 'Selected' may result from assessors being contracted, employed, authorised, recognised or

Section 9 – Appendices

9.1 Certification assessment criteria
9.2 Self-assessment form
9.3 Nomination form
9.4 Declaration form and checklist
9.5 Assessor COI declaration and confidentiality agreement
9.6 Observer affirmation
9.7 Application for renewal of Certification

These documents can be found on the HREP as separate documents to download.