ACI NSW Agency for Clinical Innovation

Responsible Governance, Management and Conduct of Research

An ACI Framework

A comprehensive outline to ensure that all research undertaken by, on behalf of, or in partnership with the ACI meets the highest ethical, scientific, regulatory and professional standards. This framework is set out in three broad sections to address the governance, management and conduct of research.

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EXECUTIVE SUMMARY

Undertaking and sourcing relevant, high quality research which informs its mandate, functions, strategic plan and priorities is an important objective of the NSW Agency for Clinical Innovation (ACI). The ACI Research Framework provides a comprehensive outline to ensure that all research undertaken by, on behalf of, or in partnership with the ACI meets the highest ethical, scientific, regulatory and professional standards. This framework is set out in three broad sections to address the governance, management and conduct of research.

The overarching governance of ACI research is provided by the ACI Research Advisory Committee, a sub-committee of the ACI Board. Several Research Sub-committees operate across the ACI to guide and facilitate research across the ACI Clinical Networks, Taskforces and Institutes consistent with the overarching framework. Leadership for the management and conduct of research activity at the ACI lies with the Clinical Program Design and Implementation (CPDI) portfolio of the ACI, with the CPDI Director and Research Manager having major responsibility.

Whilst the ACI is inherently supportive of innovation and the significant role of health and medical research, decisions must be made to prioritise what research the ACI is in a position to support. Generally, the ACI will prioritise support for research that: 1. is directly relevant to our Strategic Plan; 2. has a greater focus on translation to clinical practice or to population health; and / or 3. improves our knowledge of methods for optimising change across the health system.

The discrete research activity of the ACI is broadly grouped under three categories, each with separate application and approval processes as follows:

1. **Strategic Research** will be commissioned by the ACI as needed to address gaps in knowledge and the strategic priorities of the ACI. Research priorities will be communicated externally and invitations extended to apply for funding for an ACI Strategic Research Grant. Submissions will be reviewed against agreed criteria by an evaluation panel as per established procurement processes of the ACI.
2. **Partnership Research** will be entered into where researchers, clinicians or other individuals or groups request support from the ACI, usually cash or in-kind, for competitive research funding. Requests will be considered through a brief Research Proposal which will be considered by the ACI twice each year (usually March and September). Where projects will receive peer review by an external funding agency the ACI Executive will review and agree on any support from the ACI. Where the support being requested is for full project funding and / or the project will not be subject to peer review through other mechanisms the project will be reviewed by an evaluation panel as per established procurement processes of the ACI.
3. **Supported Research** includes occasions where researchers approach the ACI to help communicate / promote their project, request reputational support, or invite the ACI staff or Network Members in their connection with the ACI to be investigators on a project or to participate in the research. In the first instance, these requests will be reviewed by the Clinical Network Manager and Network Chair(s) and if they support the request they will forward it to the relevant Portfolio Director for review and recommendation.
4. **Externally-funded research** includes projects undertaken at ACI and by ACI staff with funding from external agencies, such as the NHMRC.

All research undertaken by, on behalf of, or in partnership with the ACI must adhere, where appropriate, to national and state codes, standards, guidelines and directives, to ensure the highest ethical, scientific, regulatory and professional standards.

1. INTRODUCTION

1.1 The Agency for Clinical Innovation

The Agency for Clinical Innovation (ACI), together with the Bureau of Health Information, the Cancer Institute NSW, the Clinical Excellence Commission, the Health Education and Training Institute and NSW Kids and Families is one of the six Pillars of NSW Health. Established in January 2010, the ACI is a Board governed statutory health organisation established under the Health Services Act 1997. It is the lead Government agency in NSW Health that drives continuous improvement and innovation in the way care is provided to patients in the NSW health system.

The ACI works with doctors, nurses, other health professionals, managers, researchers and consumers to promote improvements in health service delivery and to translate innovative ideas into sustainable system-wide changes. The ACI's 38 Clinical Networks, Taskforces and Institutes each have a specific clinical focus, e.g. aged health, pain management, nuclear medicine, stroke, ophthalmology, trauma management, emergency care and neurosurgery.

The ACI undertakes or sources relevant, high quality research which informs its mandate, functions, strategic plan and priorities and provides reports on progress to the Research Advisory Committee, established in late 2010.

1.2 Health and medical research across NSW – the current landscape

In Australia, at both national and state levels, there has been an increasing recognition in recent years of the value health and medical research can have in informing health policy, influencing health reforms, modifying structures and processes that are amenable to change and ultimately improving patient experiences and outcomes.

The 2012 NSW Health and Medical Research Strategic Review, together with the NSW Government's Response present an overarching vision that 'NSW will have a global reputation as a resilient, innovative centre of excellence for health and medical research that strongly supports a high-quality health system that is highly responsive to scientific advances and that generates health, social and economic benefits for the state and beyond' [1,2]

The role health and medical research can have in improving health is further emphasised in the Strategic Review of Health and Medical Research in Australia Consultation Paper. This Paper describes the Australian Government's endeavour to 'ensure that its investment [in health and medical research] is used wisely and equitably so that all Australians benefit through better health outcomes' [3.]

These reviews have established a strong platform for developing health and medical research capabilities. A platform to which the ACI is well placed to make a significant contribution.

The ACI is excellently positioned to work with our clinicians and the community to capture research evidence, translate this evidence into practice and examine the effectiveness and applicability of various strategies for supporting implementation of innovations. Much of the published literature on research translation focuses on local level change in practice. The ACI is in a sound position to better understand the science and mechanisms that influence spread and take-up of evidence across the NSW health system, i.e. large system transformations.

1.3 The value of research to the work of the ACI

Health and medical research has the potential to add positively to the work of the ACI by:

- Encouraging innovation;
- Gaining relevant knowledge and understanding to support our work;
- Engaging our clinical network members;
- Promoting the work of our members and networks;
- Fostering the translation and application of research outcomes to improve the strategies of our clinical networks and implementation of models of care; and
- Influencing state-wide improvements in population health, patient experiences and health care costs.

1.4 A strategic focus for ACI research

It is essential for the ACI to take a strategic approach to the research it supports. As such, it is important to encourage:

- Research that more directly supports the priorities of the ACI and the broader health system and the gaps in knowledge of these;
- The identification, utilisation and application of existing knowledge to the development and implementation of models of care and practice guides to international standards;
- A focus on translational research, where new knowledge from research can be applied to support large scale, system wide changes;
- The establishment of transparent and robust mechanisms for agreeing research priorities and supporting the research activity of the ACI;
- More robust reporting, monitoring and evaluation of research progress and outcomes to ensure accountability for allocation of resources to research;
- Appropriate acknowledgment of the ACI, its staff and Networks, Taskforces and Institutes for their role in and achievements associated with the ACI supported research;
- More strategic and comprehensive mechanisms for communicating, promoting and embedding the results of ACI research activity.

1.5 Guiding ACI research – a research framework

While investing in health and medical research can lead to significant benefits to the work of the ACI and the wider community, it also has the potential to involve risk to participants, the organisation, and investigators. A robust, comprehensive and transparent research framework which ensures that all research meets the highest ethical, scientific, regulatory and professional standards is essential.

The research framework presented in this document is set out in three broad sections to address the governance, management and conduct of research. Within each broad section, reference is made to supporting policies and procedures that are either developed or will need to be developed over time. The priority and content of this supporting documentation will adapt to a changing environment as ACI research activity evolves.

2. THE SCOPE AND FOCUS OF RESEARCH AT THE ACI

2.1 Health and medical research, translation and implementation

For the purpose of this research framework, the research activity of ACI is broadly termed health and medical research. The meaning of research is that used in the Australian Code for the Responsible Conduct of Research (2007): 'original investigation undertaken to gain knowledge, understanding and insight'[4].

In making decisions regarding which research the ACI will support, it is essential to appreciate that the ACI will prioritise support for research that:

1. is directly relevant to the ACI's Strategic Plan;
2. has a greater focus on translation to clinical practice or to population health; and / or
3. improves the ACI's knowledge of methods for optimising change across the health system. Further, it should be noted that the ACI will prioritise support for research that is:
    1. **Relevant.** The research is clearly aligned the mission of the ACI. The research provides new knowledge to inform the strategic priorities of the ACI and / or our Networks, Taskforces and Institutes and / or areas of importance as identified by the NSW Ministry of Health.
    2. **Scientifically excellent**. The project aims, research questions and hypotheses are clearly articulated and will address the research. The methods, data collection(s) and data management plans are clearly articulated and appropriate to meet the objectives of the research.
    3. **Innovative, collaborative, spans across disciplines and provides a forum for engaging consumers, clinicians and researchers**.
    4. **Feasible**. The proposed research and timelines are manageable. The proposed investigators have appropriate experience in the field of research. The proposed investigators are capable of achieving the proposed project and able to deliver the anticipated outcomes.
    5. **Sensible allocation of resources**. The commitment of the ACI in terms of cash or in-kind support for the research is deemed appropriate and a priority.
    6. **Committed to translation**. The researchers support rapid uptake and adoption of findings into practice and policy. The project encompasses the whole spectrum of research and translation from 'bench to bedside' and 'bedside to system-wide uptake into practice'. The research has the potential to influence large scale, system-wide improvements in patient experiences, patient outcomes and / or health systems.

Figure 1 illustrates the main steps in the continuum the ACI adopts for using existing or new evidence to innovate, influence practice and drive system-wide improvements.

Figure 1. The use of knowledge at the ACI to influence health system change

2.2 Discrete research activity of the ACI

For the purpose of this research framework, the discrete research activity of the ACI is broadly grouped under three categories as follows:

1. Strategic Research commissioned by the ACI to address gaps in knowledge and the strategic priorities of the ACI. These projects will be developed and led by members of the ACI staff, clinicians in their role as Members of the ACI Clinical Networks, Taskforces and Institutes and / or external research agencies commissioned by the ACI. The ACI staff may also be involved in the administrative or scientific aspects of the project.
2. Partnership Research where researchers, clinicians or other individuals or groups approach the ACI or our Networks, Taskforces and Institutes to partner in a significant research project, usually requiring the ACI support (cash or in-kind) for competitive research funding such as NHMRC Partnership Projects, Project Grants or Program Grants or ARC Linkage Grants.
3. Supported Research where researchers approach the ACI to:
    1. help communicate / promote their project (e.g., distribute an invitation or information, include information on our website);
    2. request reputational support, e.g., through an endorsement letter; and / or
    3. invite the ACI staff or Network Members in their connection with the ACI to be Associate or Chief Investigators on a project or to participate in the research.

2.3 Other non-discrete research activity of the ACI Clinical Networks, Taskforces and Institutes

The ACI Clinical Networks, Taskforces and Institutes will as a part of their routine work undertake or commission pieces of work that could by definition be labelled research. For the purpose of this framework, these projects will be considered outside the scope of discrete research. These projects may include needs assessments or diagnostics for program planning or guideline development, literature reviews, program evaluation or quality assurance or improvement activities.

2.4 Research independent of the ACI

Research undertaken by Clinical Network, Taskforce and Institute Members, as a result of existing relationships or structures that are independent of their association with the ACI is not included in the groupings of discrete research activity of the ACI. These research projects will be governed by the rules and obligations of the individual's institution and any decision to enable the ACI staff member(s) to participate in such projects rests with the ACI Executive.

3. RESEARCH GOVERNANCE

3.1 Overarching governance

A Research Committee, a sub-committee of the ACI Board, was established in late 2010. The objective of this committee is to advise the Board on the priority, quality and relevance of research available, undertaken or proposed to be undertaken by, on behalf of, or in partnership with the ACI, taking into account the roles and responsibilities of the ACI as set out in the Determination of Functions.

Membership of this committee includes: at least two Board members with a background in research; at least two independent members with a background in clinical or health services research; Chair of the ACI Board (ex officio); the ACI CEO or delegate (ex officio); and the Director, Clinical Program Design and Implementation (ex officio).

Reporting to the ACI Board, this committee has as its main functions to:

- Provide advice and oversight on the establishment and implementation of an appropriate, robust and transparent research framework for the ACI that is consistent with the mission of the ACI and meets strategic priorities.
- Provide advice and oversight on the policies and processes to ensure the responsible conduct of research undertaken or proposed to be undertaken by, on behalf of, or in partnership with the ACI, including data management, scientific integrity, ethical clearances, protecting participants, intellectual property and authorship.
- Provide advice on and encourage the prioritisation of research activity, particularly translational research, that informs the core business of the ACI and / or which underpins and informs each of the clinical networks for which the ACI has stewardship.
- Establish and provide advice on the policies and processes for managing applications for financial support for research activity of third parties and partnerships with funding implications, in-kind or otherwise for the ACI.
- Provide ongoing monitoring, review and quality assurance of the progress and outcomes of the 'flagship' research projects of the ACI as well as other projects of significance identified from time to time.
- Review and advise on the communication strategy for research activities and outcomes, including communication with government, the community, clinicians and health managers.

3.2 Research sub-committees across the ACI

Several ACI Clinical Networks, Taskforces and Institutes have already established Research Sub-committees. Whilst these committees are not sub-committees of the ACI Research Committee or Board, it will be a requirement that their activities adhere to this framework. Processes will be established to encourage communication across these committees, implement efficiencies, share expertise, limit unnecessary duplication of resources and encourage research collaboration across disciplines.

3.3 Leadership for implementation

Leadership for the management and conduct of research activity at the ACI lies with the Clinical Program Design and Implementation (CPDI) portfolio of the ACI, with the CPDI Director and Research Manager having major responsibility. These responsibilities include:

- Leading the establishment, implementation and monitoring of policies, procedures and strategies to ensure implementation of the agreed research framework for the ACI.
- Monitoring and advising on the alignment of research projects with the priorities and purposes of the ACI, especially with respect to the development and implementation of models of care.
- Ensuring that every effort is made to translate research findings into the clinical and health service settings and that the impact is evaluated and reported upon.
- Providing advice and support to the ACI staff and collaborating researchers on the preparation and management of applications for financial support for research activity.
- Providing advice and support to the ACI staff and collaborating researchers on the development of research ideas and projects, including developing research questions, establishing project scope and designing data collection tools.
- Providing ongoing monitoring, review and quality assurance of the progress and outcomes of all research undertaken by, on behalf of, or in partnership with the ACI.
- Providing advice and support to the ACI staff and collaborating researchers on the responsible conduct of research, including scientific integrity, ethical clearances, protecting participants, intellectual property and authorship.
- Providing advice and support to the ACI staff and collaborating researchers on the communication of research activities and outcomes.

3.4 Shared responsibilities

All of the ACI staff, researchers, doctors, nurses, other health professionals, managers and the community involved in ACI research have a responsibility to act according to the principles and guidelines outlined in this framework.

3.5 Consumer engagement

The ACI believes that consumer engagement in research strategy is key to ensuring its relevance and value. As such, the ACI strongly encourages meaningful engagement of consumers in the identification of research questions, development of methods and dissemination of findings in all research it supports.

4. RESEARCH MANAGEMENT

The following outlines the key steps in the commissioning, approval and facilitation of ACI research across the three broad categories of discrete research activity described above. Figure 2 illustrates this process. The principles that underpin the responsible conduct of this research are common across all research types and are presented in the following section.

4.1 Strategic research

From time to time the ACI will identify research questions directly relevant to its Strategic Plan. On these occasions, these research priorities will be communicated externally and invitations extended to apply for funding for an ACI Strategic Research Grant. Invitations will include detail on the eligibility criteria, amount and duration of the research and targeted application forms will be provided. Submissions will be reviewed against agreed criteria by an evaluation panel as per established procurement processes of the ACI. The evaluation panel will be comprised primarily of relevant ACI staff with external expertise sourced as required.

4.2 Partnership research

The ACI may provide financial and / or in-kind support to resource a research project in full or in part where an application for additional funding from other sources is being made (e.g. an NHMRC Partnership Project or ARC Linkage Grant). On these occasions, the individual primarily responsible for proposing the partnership research will be required to complete a brief Research Proposal (Appendix 1). This proposal will collect information to assess the relevance and appropriateness of proposed projects, including information on:

- Chief and collaborating investigators
- Project description, including aims, objectives and expected outcomes
- Project approach, including data collections and main outcomes measures
- Significance, innovation and translation, including how the project will be of benefit to the ACI and / or the NSW Health System, how the design, aims, methods and / or collaborative processes are novel and innovative and how the project will be translated into improved clinical practice and policy
- Timeline and budget and resource implications for the ACI and its staff

Requests will be considered twice each year (usually March and September). In the first instance, the Research Proposal will be reviewed by the Clinical Network Manager and Network Chair(s) and if they support the project they will forward it to the ACI Research Manager to collate.

Where projects will receive peer review by an external funding agency the ACI Executive will review and agree on any support from the ACI. Where the support being requested is for full project funding and / or the project will not be subject to peer review through other mechanisms the project will be reviewed by an evaluation panel as per established procurement processes of the ACI. The evaluation panel will be constituted primarily of relevant ACI staff with external expertise sourced as required.

4.3 Supported research

All requests for research support, including help to communicate / promote a project, requests for an endorsement letter and invitations for ACI staff or Network, Taskforce or Institute Members in their connection with the ACI to be investigators on a project or participate in the research, must be in writing. In the first instance, the request will be reviewed by the Clinical Network Manager and Network Chair(s) and if they support the request they will forward it to the relevant Portfolio Director for review and recommendation. For projects spanning more than one Network or not directly fitting within one specific Network, the proposal will be forwarded to the CPDI Director for review. Where the Director would like additional advice, they can take the request to the ACI Executive for comment. The ACI Research Manager must be notified of any recommendation for support and this will be logged and reported to the ACI Executive and Research Committee on a quarterly basis.

4.4 Other non-discrete research activity of the ACI Clinical Networks, Taskforces and Institutes

A decision to undertake data collections or other non-discrete research as a part of the routine work of the ACI is the responsibility of the Network, Taskforce or Institute Manager and their Portfolio Director. The ACI Research Committee will not, apart from occasions of exception, monitor and provide advice on these projects. The ACI Research Manager will maintain a repository of these projects and ensure the ACI staff and other interested stakeholders are aware of these activities where appropriate. See Figure 2.

4.5 Communication of research findings

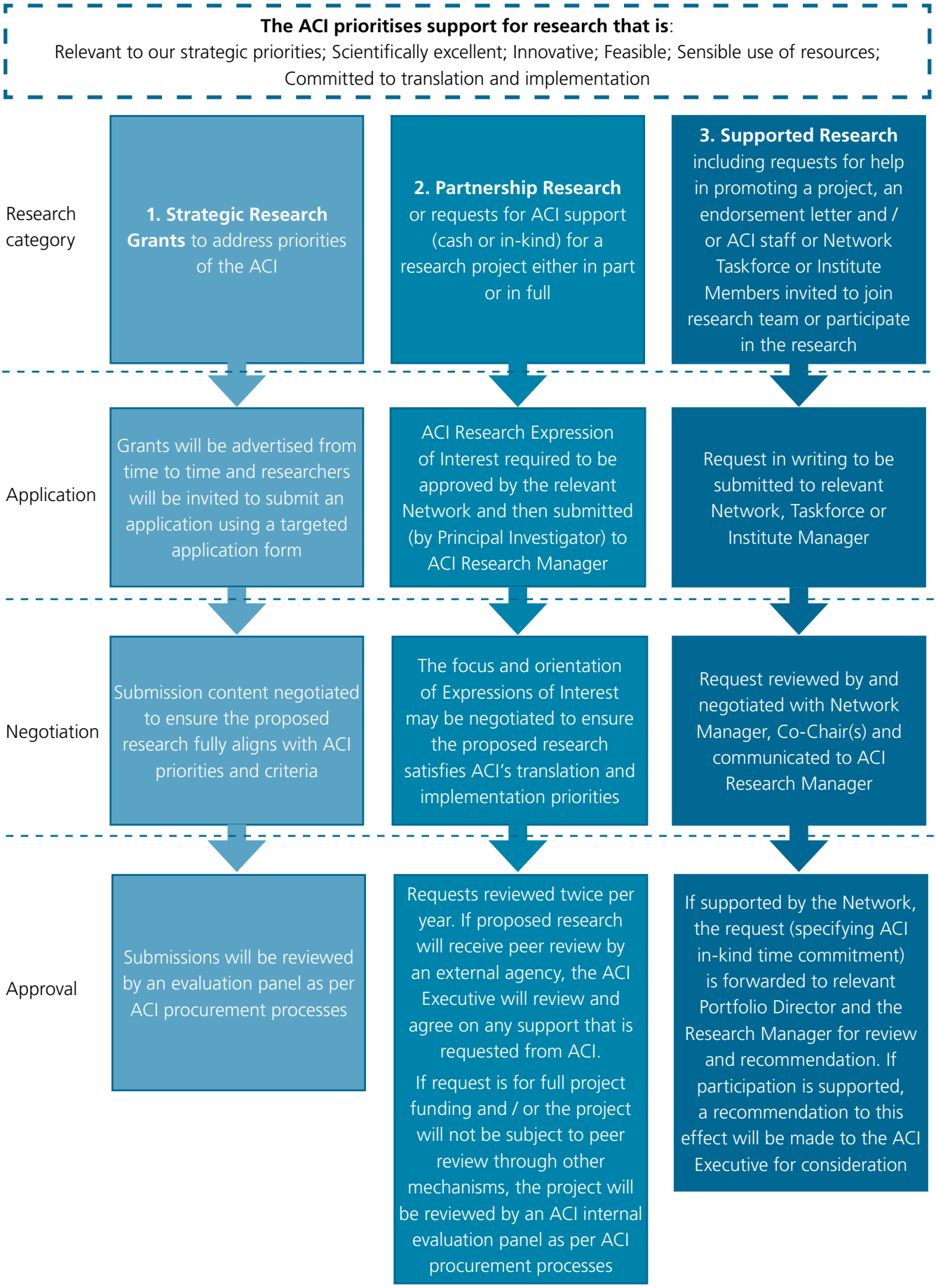
The ACI strongly believes that publication and dissemination of research outcomes and findings, whether favourable or unfavourable, is an important aspect of the research process, passing on the benefits to other investigators, professional practitioners and the wider community. As such, all researchers undertaking projects in partnership with the ACI must be committed to publishing results and disseminating research findings in an accurate and timely manner.

4.6 Accountability

It will be essential to evaluate research processes and outputs to ensure ACI endorsed research has a positive return on investment for the ACI. A set of Research Key Performance Measures will be established for all research projects undertaken by, on behalf of, or in partnership with the ACI. The emphasis with these will be on need, application, implementation and evaluation, including evidence of:

- the ACI facilitating relevant research (number of projects commenced and completed, collaborative research projects, the ACI investment both cash and in-kind, external research grant funding)
- research supported by the ACI is delivering useful outcomes (peer review publications, conference presentations, reports or media articles resulting from research projects)
- research supported by the ACI is contributing to the objectives of the ACI Strategic Plan, including being used to inform program development
- the application of research findings contributing to the improvement of patient experiences and practice outcomes.

Figure 2. Process for approving the ACI involvement in research, monitoring research activity and approving research outputs



4.7 Managing complaints and allegations of research misconduct

Before commencement, it is a requirement that all research of the ACI seeks review and approval from an appropriate Human Research Ethics Committee (HREC). In the first instance, any complaints and / or deviations from ethical approvals will be managed by the approving HREC. If the issue is outside the remit of the approving HREC, the ACI may outsource management of the issue to a suitable entity.

4.8 Monitoring compliance with this framework and associated policies

It will be the responsibility of the ACI Research Manager to monitor adherence to this framework and associated policies. Any concerns regarding non-adherence will be referred to the CPDI Director in the first instance and escalated to the ACI Executive if needed for further management.

4.9 Training staff in their obligations under this framework

It will be the responsibility of the ACI Research Manager to ensure reference to this framework is included in the usual orientation processes for all ACI staff. The ACI Research Manager will maintain a repository of all relevant materials and if needed, will identify the need for additional staff training on either an individual or groups basis.

5. RESEARCH CONDUCT

5.1 Adherence to relevant codes and standards

All research undertaken by, on behalf of, or in partnership with the ACI must adhere, where appropriate, to national and state codes, standards, guidelines and directives, to ensure the highest ethical, scientific, regulatory and professional standards. A list of these relevant codes and standards is provided in Appendix 2.

5.2 Application of relevant codes and standards in practice

Application of the central principles covered by the relevant codes and standards, especially the NHMRC National Statement on Ethical Conduct of Research Involving Humans (2007) 4, ensure that in practice all research undertaken by, on behalf of, or in partnership with the ACI must:

- Obtain and maintain ongoing approval from a **relevant human research ethics committee** and at all times comply with the conditions of this approval.
- Disclose any potential, perceived or actual **conflicts of interest** and deal with these conflicts appropriately.
- Be of excellent **scientific quality**. The research must be designed or developed using methods appropriate for achieving the aims of the research proposal and based on a thorough study of current literature, as well as previous studies.
- Have **excellent leadership**. ACI research projects should be conducted or supervised by persons or teams with suitable experience, qualifications and competence that are appropriate for the research.
- Encourage **collaboration** not duplication.
- Be **appropriately resourced**. ACI research projects must be conducted using appropriate facilities and resources, to support the successful undertaking of the research.
- **Protect participants**. Participants must be: treated with respect in all of their dealings with the ACI and its researchers; given the opportunity for written informed consent prior to participating in a research project; treated in accordance with the terms of their written consent, including maintenance of confidentiality of their identity and any information they provide; aware that their participation is voluntary and they are free to withdraw from a research project at any time without impact on any future care; not over-burdened by excessive requests for and involvement in research; and given appropriate consideration in the case of any concerns or complaints.
- Ensure **confidentiality of information**. All ACI research must ensure that the personal information of participants is only used for the purposes for which consent to its collection was given and all necessary measures to safeguard the privacy and confidentiality of the individual providing the information must be observed. Further, all reports or publications resulting from ACI research must not be presented in a way that an individual's identity can be determined.
- Establish mechanisms for **appropriate record keeping**.
- Ensure **security of research data and information**. A range of administrative, logical and physical controls must be in place to manage the security of ACI research data and such controls should be subject to regular assessment and review. Adherence to the ACI Database Governance Framework is essential. This framework and the relevant controls address issues including: secure management and storage of hard copy research information; secure storage of databases and datasets; signing of confidentiality agreements by researchers; safe transfer of data between research sites; and controls around release and use of data by third parties.

- Maintain appropriate **training of staff and researchers**. All personnel associated with ACI research projects need to be familiar with their responsibilities in relation to this Framework and where required appropriate training will be provided, for example, in research methods, the requirements of data handling, NSW Goverment privacy legislation and good practice. At present (October 2014), the Office of Health & Medical Research, in collaboration with the CEC and ACI, is updating the ethics approval process to be followed by staff employed by state government agencies.
- Commit to **regular reporting** on progress and achievements to the ACI Research Committee and Board as required.
- Be committed to **publishing results and disseminating research findings in an accurate and timely manner**. Publication and dissemination of research outcomes and findings, whether favourable or unfavourable, is an important aspect of the research process, passing on the benefits to other investigators, professional practitioners and the wider community.
- Support appropriate **intellectual property**. In line with *Policy Directive PD2005_370 Intellectual Property* Arising *from Health Research Policy – NSW Department of Health*, all ACI research projects must identify, record and (if relevant) register and protect intellectual property owned by them which is derived from research.
- Support appropriate **authorship rights**. All ACI research projects will need to conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications by the International Committee of Medical Journal Editors. In brief, authorship of publications should be based on substantial contribution in a combination of: 1. conception and design of the project; 2. analysis and interpretation of research data; and 3. drafting significant parts of the work or critically revising it so as to contribute to the interpretation. A separate policy supporting appropriate authorship of ACI research is included in Appendix 3.
- Support appropriate **acknowledgements**. Acknowledgment of the ACI is mandatory in all external communications and publications of research progress and findings where the research has been undertaken under the auspices of the ACI and / or led by the ACI Network Members as a result of their connection with the ACI.A separate policy for supporting appropriate acknowledgment of the ACI in research activity is included in Appendix 3.
- Meet **internationally recognised research integrity standards**. All research conducted with the support of ACI is to adhere to internationally recognised research integrity standards as articulated by the NHMRC (see: http://www.nhmrc.gov.au/health-ethics/research-integrity).

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APPENDIX 1
RESEARCH EXPRESSION OF INTEREST

The application process

The Agency of Clinical Innovation (ACI) invites Expressions of Interest from researchers interested in partnering with ACI. Three kinds of research are supported: Strategic Research (commissioned and funded by ACI and separately advertised), Partnership Research (carried out with ACI funding and competitive research funding, and/or with in-kind support), and Supported Research (conducted with ACI and clinical network support). The present form applies to Partnership and Supported Research only.

ACI research priorities

ACI targets the design, evaluation and implementation of innovative models of patient care. ACI operates through effective partnerships to produce innovative health care provided with operational excellence. The full scope of ACI's responsibilities and directions are set out in its 2012-2015 Strategic Plan and Operational Plan 2013-2014. The research priorities that emerge from these Plans centre on:

- Relevance: the research aligns with ACI's mission;
- Scientifically excellent: the research meets international theoretical and methodological standards;
- Innovative and collaborative: the research spans across disciplines and provides a forum for engaging consumers, clinicians and researchers;
- Feasible: the research is manageable, realistic, supported by appropriate experience and able to deliver proposed outcomes;
- Economic: the research is deemed to involve an appropriate judgment about resource expenditure;
- Translational: the research extends to uptake, adoption and evaluation of findings 'from bench to bedside', and 'from bedside to system'.

Research approach

ACI's translational priority has implications for research design and methodology. Generating knowledge and putting knowledge into practice require different theories and methods. Research studies submitted to ACI are therefore expected to be multi-method studies, deploy realist evaluation, and draw on disciplines and theories from both the clinical and health sciences, and the organisational and social sciences.

Research conduct

All research undertaken in partnership with ACI must adhere to relevant standards of research conduct. Proposals and research designs should be developed with reference to the NHMRC-ARC Standards of Academic Conduct.

Results sharing

All researchers awarded funding through ACI agree to make themselves available to present their progress and findings at a public forum organised by ACI on an annual basis.

Research expression of interest form

This form is designed to assist the NSW Agency for Clinical Innovation (ACI) consider research expressions of interest in a consistent and transparent manner. It is required to be filled out for all new research projects where there is a request for ACI financial or in-kind support.

If you face any difficulties whilst completing this from or you would like to discuss your proposed project in more detail, please do not hesitate to contact Rick Iedema at rick.iedema@aci.health.nsw.gov.au or 02 9464 4672.

1. Name of proposed project

2. Name and contact details for lead individual proposing the research

Family name		Title:
Given name		
Telephone		
Email		
Current Position		
Organisation		

3. Other investigators involved in the proposed research

Name	Position and Organisation

4. Type of research proposed

☐ Partnership research

☐ Supported research

5. Support from Clinical Network(s), Institute(s) or Taskforce(s) of the ACI

Please include below and / or attach proof that you have discussed your project with relevant Clinical Network(s), Institute(s) or Taskforce(s) of the ACI, and with ACI's Research Manager, and that all endorse your project as a priority for ACI to undertake to benefit the NSW health system and direct patient care.

6. Project description

Please provide a succinct, plain English description of the project, including aims, objectives and expected outcomes (maximum 300 words).

7. Research approach

Please provide a succinct, plain English description of the methods for this project, including data collections and main outcome measures (maximum 200 words).

8. Significance and innovation

Please provide a succinct, plain English description (maximum 200 words) of:

- Why the proposed project is significant and will be of benefit to ACI and / or the NSW Health System
- How the design, aims, methods and / or collaborative processes are novel and innovative

9. Feasibility

Please provide a succinct, plain English description (maximum 100 words) of the project's feasibility.

10. Translation and integration

Please provide a succinct, plain English description (maximum 200 words) of how the project's outcomes will:

- inform or yield new models of care
- contribute to strengthening care integration
- evaluate the realisation of such models of care and care integration.

11. What are the expected start and completion dates for the proposed project?

12. What are the estimated total budget for the proposed project?

13. Please list the main budget items, including a rationale for inclusion

14. What funding has been secured or is being sought for the project?

Include if relevant any requests being made of ACI for financial support of the proposed project

Source of funds / grant type	Amount	Status of funding Indicate one option per line		
		Confirmed	Under negotiation	Still to be sought
		☐	☐	☐
		☐	☐	☐
		☐	☐	☐
Total				

15. Please describe the support you are requesting of ACI

Support type	Yes	No	Details
Partnership – cash contribution	☐	☐	If yes, please add detail on total amount, over what years, amount per year
Partnership – in kind contribution	☐	☐	If yes, please provide detail on nature of in-kind support, e.g. brokerage, facilitation, distribution of surveys, dollar estimate of in-kind support, total and by each year of the project

16. References

17. Track record of research team

Please provide a one page track record description for each investigator, including their role in the project, their qualifications and skills relevant to the project, career achievements and most significant publications.

APPENDIX 2

CODES AND STANDARDS TO WHICH ACI RESEARCH MUST CONFORM

Governance

- Research Governance in NSW Public Health Organisations (2011) by NSW Health, which summarises the principles, standards and requirements for the responsible conduct of quality research. It also clarifies the responsibilities and accountabilities of key parties involved in research taking place in NSW Public Health Organisations

Conduct

- The National Health and Medical Research Council Act (1992) (Cth), under which the provision of funding through the NHMRC Funding Schemes is conditional on recipients complying with guidelines issued by the NHMRC relating to the conduct of medical and health research
- The National Statement on Ethical Conduct in Human Research (2007) by the National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee
- The Australian Code for the Responsible Conduct of Research (2007) by the National Health and Medical Research Council, Australian Research Council, and Universities Australia
- The NSW Supplement to the National Statement on Ethical Conduct in Human Research which provides guidance on how NSW laws and other requirements of NSW Health relate to the requirements of the National Statement
- The NHMRC Research Integrity standards (see: http://www.nhmrc.gov.au/health-ethics/research-integrity, and see Appendix 4).

Privacy and confidentiality

- The *Commonwealth Privacy Act* (1988), which regulates the use of personal information by the private sector in NSW including non-government organisations and private health sector providers
- The *Statutory Guidelines on Research* issued by the NSW Privacy Commissioner under the Health Records and Information Privacy Act 2002 (NSW), which regulates use of personal health information in the NSW public and private sectors

Research with Aboriginal communities

- *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003) by the National Health and Medical Research Council, Australian Research Council
- *Guidelines for Ethical Research in Australian Indigenous Communities* (2011) by the Australian Institute of Aboriginal and Torres Strait Islander Studies

Research with animals

- *Australian code of practice for the care and use of animals for scientific purposes* (2004) by the National Health and Medical Research Council

Health information and research data

- Policy Directive PD2005_593 *Privacy Manual* (Version 2) – NSW Health, which provides a guide to the legislative obligations imposed on the health system by the Health Records and Information Privacy Act 2002 (NSW)
- Other pieces of legislation that impose controls on when and how information can be used and disclosed in the health system, including: *Health Administration Act* 1982 (NSW); *Mental Health Act* 2007 (NSW); *Public Health Act* 1991 (NSW); *Government Information (Public Access) Act* 2009; and *Health Care Liability Act* 2001
- Policy Directive PD2006_077 *Data Collections – Disclosure of unit record data held for research or management of health services*, which provides guidance on disclosure of unit record data, which are held in data collections owned by the NSW Health, including those collections that are managed by an external agency on behalf of NSW Health

APPENDIX 3
GUIDE TO PUBLICATION, AUTHORSHIP AND ACKNOWLEDGMENTS FOR ACI RESEARCH

Background

ACI strongly believes that publication and dissemination of research outcomes and findings, whether favourable or unfavourable, is an important aspect of the research process, passing on the benefits to other investigators, professional practitioners and the wider community. As such, all researchers undertaking projects in partnership with ACI must be committed to publishing results and disseminating research findings in an accurate and timely manner.

Purpose

The purpose of this policy is to outline the requirements for publication, authorship and acknowledgements for any publications, reports, presentations and other disseminations that result from all research projects undertaken by, on behalf of or in partnership with the ACI.

Scope

This guide applies to all Portfolio Directors, Managers and Staff of ACI. It also applies to all members of ACI Clinical Networks, Institutes and Taskforces and other individuals involved in the publication and dissemination of the outcomes of all research undertaken by, on behalf of or in partnership with the ACI.

Associated documents

Policy Directive. Research Governance in NSW Public Health Organisations (2011) issued by NSW Health. This policy summarises the principles, standards and requirements for the responsible conduct of quality research. It also clarifies the responsibilities and accountabilities of key parties involved in research taking place in NSW Public Health Organisations http://www0.health.nsw.gov.au/policies/gl/2011/pdf/GL2011_001.pdf

Guidelines

All investigators involved in undertaking research by, on behalf of or in partnership with the ACI must adhere to the following:

1. **Commit to publishing** results and disseminating research findings in an accurate and timely manner, regardless of whether the findings are favourable or unfavourable.
2. Support appropriate **authorship rights**. Authorship on research publications will be made based on the guidelines for authorship by the *International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts to be Submitted to Biomedical Journals (2010*). See Attachment and http://www.icmje.org/urm_main.html. In brief, authorship on publications should be based on substantial contribution in a combination of: 1. conception and design of the project; 2. analysis and interpretation of research data; and 3. drafting significant parts of the work or critically revising it so as to contribute to the interpretation.
3. Support appropriate **acknowledgements**. Acknowledgment of ACI is mandatory in all external communications and publications of research progress and findings where the research has been undertaken under by, on behalf of or in partnership with the ACI and / or led by Members of ACI Clinical Networks, Institutes and Taskforces as a result of their connection with ACI.
4. Support **recognition of contributions**. Contributions to a publication will either be recognised as a named author or as a member of the research group or Clinical Network, Institute or Taskforce where relevant.
5. Support **students**. Students working on the project will be entitled to first authorship on publications that arise directly from their studies.
6. All publications, reports, presentations and other disseminations must acknowledge the **funding source(s)** of the research as well as the **ethical approval**. Suitable text is as follows: This research was supported by <insert funding body> through their <insert funding scheme> (ID: <insert project reference number>). The research protocol was approved by the <insert HREC name> in <insert date> (ID: <insert ethical approval reference number>).
7. For research **commissioned and / or directly funded by ACI**, it will be a requirement that ACI is included in the Acknowledgements of all publications, reports, presentations and other disseminations for providing funding support.
8. Discussion of a **publications plan** should be included as a standing agenda item at any investigator meetings associated with research projects of ACI. When a new publication is discussed, a Lead Author will be identified. The Lead Author will contact all investigators, including ACI staff where relevant, and invite them to join the writing group for the paper.
9. As a matter of courtesy, and to assist where relevant with interpretation, all proposed publications, reports, presentations and other disseminations of ACI research must be submitted for **technical review** prior to being published. The relevant Portfolio Director is responsible for providing approval prior to submission.

Attachment
Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research: Authorship and Contributorship

Byline Authors

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications (1). *An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors' ability and integrity.* In the past, readers were rarely provided with information about contributions to studies from persons listed as authors and in Acknowledgments (2). Some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole.

While contributorship and guarantorship policies obviously remove much of the ambiguity surrounding contributions, they leave unresolved the question of the quantity and quality of contribution that qualify for authorship. The ICJME has recommended the following criteria for authorship; these criteria are still appropriate for journals that distinguish authors from other contributors.

- Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Journals generally list other members of the group in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.
- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Some journals now also request that one or more authors, referred to as "guarantors," be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

Increasingly, authorship of multicenter trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributorship decisions or to arbitrate conflicts related to authorship.

Contributors listed in acknowledgments

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chairperson who provided only general support. Editors should ask corresponding authors to declare whether they had assistance with study design, data collection, data analysis, or manuscript preparation. If such assistance was available, the authors should disclose the identity of the individuals who provided this assistance and the entity that supported it in the published article. Financial and material support should also be acknowledged.

Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship may be listed under such headings as "clinical investigators" or "participating investigators," and their function or contribution should be described—for example, "served as scientific advisors," "critically reviewed the study proposal," "collected data," or "provided and cared for study patients." Because readers may infer their endorsement of the data and conclusions, these persons must give written permission to be acknowledged.

APPENDIX 4
PROCESS FOR MANAGING SUSPECTED MISCONDUCT IN RESEARCH

Scope

The process outlined in this document applies to all Portfolio Directors, Managers and Staff of ACI. It also applies to all members of ACI Clinical Networks, Institutes and Taskforces and other individuals involved in the conduct of research undertaken by, on behalf of or in partnership with the ACI.

Definition

For the purpose of this document, the definition of misconduct in research has been adapted from the University of Western Sydney http://policies.uws.edu.au/view.current.php?id=00166 and includes, but is not limited to:

- fabrication, falsification, or deception in proposing, carrying out or reporting the results of research
- plagiarism in proposing, carrying out or reporting the results of research
- failure to declare or manage a serious conflict of interests
- avoidable failure to follow research proposals as approved by a research ethics committee, particularly where this failure may result in unreasonable risk to humans, animals or the environment or breach of privacy
- wilful concealment or facilitation of research misconduct by others
- misleading ascription of authorship
- intentionally and without authorisation taking, sequestering or materially damaging any research-related property of another
- deliberately conducting research without required human ethics committee approval
- conducting research involving animals without required animal ethics committee approval
- risking the safety of human participants or the wellbeing of animals or the environment.

Principles for dealing with suspected misconduct in research

- All investigations of alleged misconduct in research will be conducted with due regard for procedural fairness.
- Where allegations concern more than one person, these allegations will be investigated separately for each person.
- To ensure that both the person making the allegation and the person against whom the allegation has been made are given adequate protection, all individuals dealing with an allegation will observe strict confidentiality and proceed with all reasonable speed, in all stages of an investigation.
- If an allegation is found to be not substantiated, the person who was the subject of the allegation must not be treated by the ACI in any way implying that the allegation was correct.

Process

- Where the Administering Institution for the project is an external organisation, e.g. a university, the suspected misconduct of research will be managed in accordance with the policies of that institution. As a stakeholder in the research, the ACI will expect to be informed about and included where relevant in the institution's procedures.
- Where the ACI has commissioned the research, the research personnel will be governed by the rules and obligations of the individual's institution.
- Where staff of the ACI are leading the research and there are concerns of research misconduct the situation will be discussed in the first instance with the relevant Portfolio Director and then Chief Executive for further investigation. If warranted and escalation is required, support in managing the process will be sought from an established University Research Office.

ACI NSW Agency for Clinical Innovation