NSW Health and Medical Research Governance Project

Reform of the pre-approval Process

November 2014

REFORM FRAMEWORK AND ACTION PLAN

Introduction

This paper outlines the proposed framework and Action Plan for reform to the process of pre-approval of health and medical research in NSW. It builds on work already undertaken by the NSW Office for Health and Medical Research (OHMR) including the 2012 Strategic Review of Health and Medical Research and the recent discussion paper and stakeholder consultation on the options for reform.

Why reform the pre-approval process?

The role and value of health and medical research is well recognised in delivering better treatments, improving health services, supporting innovation and improving health outcomes both in hospital and in the community. In order to realise the benefits of health and medical research activity for the people of NSW, it is essential that research be embedded in all aspects of the delivery of health services. A culture of patient-focused, high quality research that is seen as complementary to the delivery of clinical care, training and education is essential to ensuring the welfare of research participants and enabling the people of NSW access to high quality, evidence based health care. Ensuring the embedding of research culture requires an ongoing partnership between agencies and organisations that conduct research or provide health services. Given the benefits of health and medical research to the community, it is critical that this activity is able to commence in a timely manner.

Developing the Reform Framework

The Reform Framework was developed through extensive consultation with stakeholders involved in all aspects of the clinical research lifecycle to identify the reform solutions that would deliver the highest value. The reform options were further tested in a series of forums and focus groups. The consultation responses received during the survey conducted in December 2014 strongly communicated a number of key themes:

1. The system is **complex** with many layers and little clear guidance or **clarity**
2. The system is **highly variable**, with advice and requirements between Public Health Organisations (PHOs), with little understanding of why this occurs or if it is necessary
3. The Site Specific Assessment (**SSA**) **and governance policies** is a major area of concern and considered a **major barrier** with little understanding of the value it adds to PHOs
4. There is too much **duplication** within the system. Duplication between sites for SSAs, duplication between the requirements of SSAs and the Human Research Ethics Committee (HREC), duplication wherein information is sought in the NEAF and duplication in post approval requirements such as annual reports. This links into….
5. Overwhelming **paperwork burden** that adds time and cost to all stakeholders in writing, reviewing and managing the documentation and processes. There is a lack of clarity on how this information is used and a lack of transparency and reporting
6. LHD's, Research Governance Officers, HRECs and their Executive Officers have little **accountability** to system users. It is difficult to raise complaints, escalate and resolve issues and there are no consequences for poor performance or non-compliance with policy.

The December 2013 Discussion Paper and consultation survey sought feedback from a wide range of stakeholder groups including researchers, commercial sponsor (sponsor) representatives, clinical trials site staff, Human Research Ethics Committee (HREC) members, Ethics Officers (EOs), Research Governance Officers (RGOs), executives in the Public Health Organisations (PHOs) and Speciality Networks as well as a range of professional bodies. Extensive feedback was provided on the current system as well as suggestions for improvement and examples of what works well. The intention of the survey was to identify and prioritise the areas of reform based on stakeholder feedback.

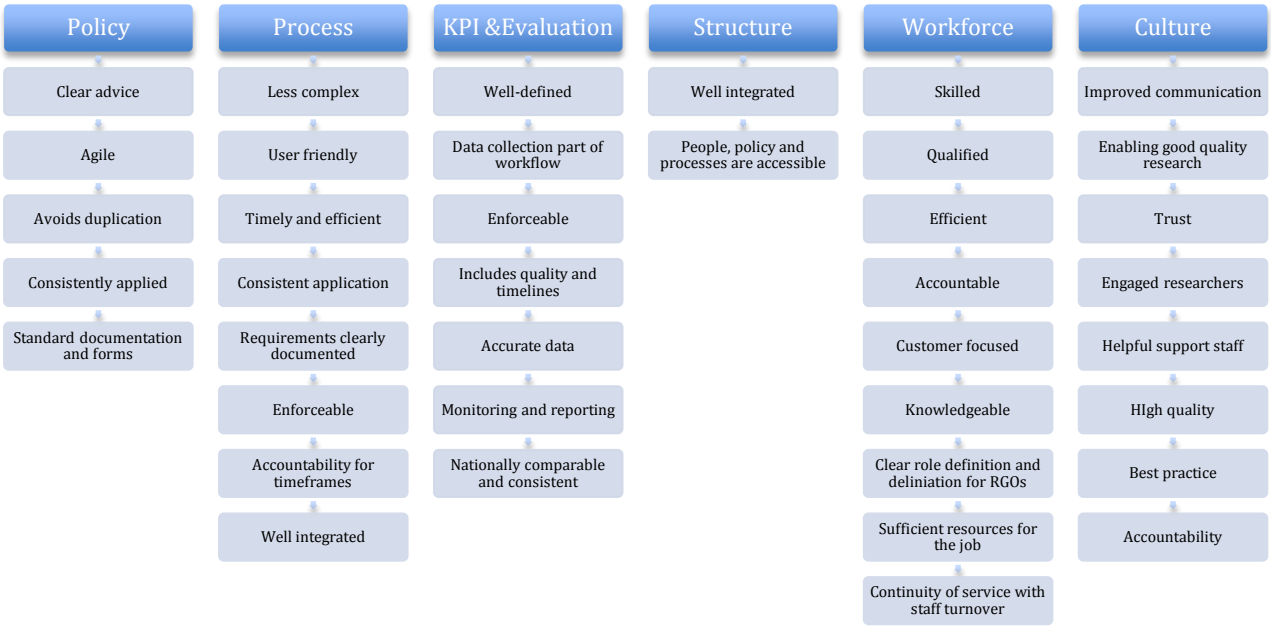
The table below summarises the highest value reforms to improving the pre-approval system as ranked by stakeholders in the survey. There was minor variation in priority between stakeholder groups, however this list encompasses the highest priority items.

Theme	Options that deliver the highest value to pre-approval system improvement
Duplication	Expand mutual acceptance model to all multicentre research, not just clinical trials
Duplication Accountability Complexity Variation Paperwork burden	Establish a central co-ordinating body through OHMR or as an independent agency that is responsible for agreed aspects of single ethical and governance review
Accountability Variation	Establish agreed, realistic performance measures and minimum standards across a number of domains including throughput, timeliness, quality (of submission and review) and customer satisfaction at the State, LHD and Research Office level
Clarity Duplication Paperwork burden	Central website that hosts all HREC and LHD governance requirements, specific forms, protocols, templates, guidance and closing dates. A "one stop shop" for HREC and governance approval in NSW public health organisations
Links with REGIS Accountability Variation Complexity Paperwork burden	Establish a single, integrated, point of access to the ethics and governance system such as the UK Integrated Research Application System (www.myresearchproject.co.uk). This system covers all approvals and permissions to conduct research, which ideally will involve integration with federal bodies such as the office of the Gene Technology Regulator (OGTR) and Therapeutic Goods Administration (TGA), who provide licencing prior to governance approval.
Complexity Duplication Paperwork burden	Review the use of NEAF if it does not provide all the information HRECs require
Duplication Paperwork burden	Amend NSW Policy to allow acceptance of HREC approval from any National Health and Medical Research Council (NHMRC)-certified HREC, including private HRECs such as Bellberry Ltd and issue clear guidance on what approvals can be accepted by NSW PHOs
Duplication Paperwork burden	OHMR or an independent agency may take responsibility for approving all CTRAs and contracts, external entity agreements and providing advice on risk management and indemnity matters.
Duplication Accountability	Matrix of governance functions developed, current processes, anomalies and duplication to be identified prior to consultation on what may be appropriate to centralise.
Accountability Variation	Agreed, consistently applied start and finish point for timeframe measurement.

Once "what needs to be fixed" had been identified and prioritised, these options were further fleshed out with stakeholders to determine the "how". The objective of the Reform Framework is to map the areas of reform, potential linkages and dependencies and to provide a framework to develop solutions in consultation with stakeholders.

Health and Medical Research Pre-Approval Process Attributes

The rich commentary in the survey provided insight into the ideal pre-approval system from the perspective of different stakeholders, although there was significant overlap between the needs of different stakeholders. The recurring themes and attributes of the model pre-approval system for NSW are outlined across the reform domains.



These attributes provide the basis for the Reform Framework and Action Plan. The success of the reform agenda can be measured against the extent that these attributes are achieved.

Evaluation of Reform Framework

The success of the Reform Framework can be measured in a number of ways:

1. Has the objective of improved timeframes to approval been met?
2. How does the pre-approval process compare with the agreed system attributes and strategic objectives from stakeholder perspectives? Have any been achieved? Do they remain relevant?
3. Have the priority areas been satisfactorily addressed?

A balanced scorecard approach was used in the stakeholder consultation to describe the desired outcomes across a number of perspectives and to narrow down the reform options during a series of focus groups. These perspectives include:

- The **customer, stakeholder or end user** defines the value proposition; this perspective reflects what is valuable to the end user. The customer value proposition is the central element to the strategy.
- **Internal processes** create and deliver the value proposition for customers or end users. The performance of internal processes are leading indicators for customer satisfaction.
- **Learning and growth or culture** objectives describe how people, technology and organisational culture combine to support the strategy.

Please note that the strategy map outlined in this paper describes the short- to mid-term priorities. The need to change the culture of research was highlighted in survey findings. This Framework does not include action items related to matters of research culture as this underpins and informs other policies and initiatives currently in development. These reforms require a more strategic approach working with PHOs, Hubs and Universities to embed research into the core business of PHOs and into the delivery of high quality care.

Due to the dominance and priority of process reform, the financial perspective of the balanced scorecard has been omitted from the strategy and framework. However, fee structure reform and financial competitiveness are addressed in other perspectives.

Strategic objectives

The strategic objectives make a number of assumptions that need to be considered when reviewing the Framework:

1. That NHMRC-certified HRECs are compliant with certification conditions and provide high quality ethical review
2. This project is focused on review, approval and monitoring processes and its scope does not extend to enhancing the ethical review undertaken by HRECs
3. Institutions have their own research strategies which include improving research quality and embedding a culture of quality research
4. The OHMR will be responsible for implementing the framework, as such the framework is focused on reform that is with the remit of OHMR.

Linking Strategy and Implementation

Following the survey analysis and identifying priority reforms, the reform areas and draft Action Plan was tested with key stakeholders through a series of focus groups. The purpose of these focused meetings was to test the feasibility of the proposed reform options and to work with stakeholders to design solutions suitable for implementation. Many options for reform were identified in the survey, however only those that were identified as high priority or high impact on timeliness of review were taken to the focus groups. The recommendations below, coupled with the high priority items from the survey form the basis for the Implementation Plan.

Focus Group	Attendees	Recommendations
Site Specific Assessment (SSA) Redesign	Clinical researchers, clinical trial co-ordinators, commercial sponsors (sponsors), HREC members, RGOs and CE delegates	• Simplification of forms • Implement the requirement for concurrent review • Provide clarify on roles and responsibilities of the Head of Department, CE/Delegate and the RGO • Improve consistency in review of SSAs through common documentation, single review of consent documentation, clarification of the scope and responsibilities of the RGO and escalation mechanisms to resolve inconsistencies in advice
Central Co-ordination of the allocation of HREC applications	Clinical researchers, clinical trial co-ordinators, sponsors, HREC members, RGOs and CE delegates Presentation given on QLD central allocation model.	• Investigate models for central allocation, including potential subcontract arrangements to states that have the existing staffing and infrastructure • Standardise forms and requirements of HRECs to support a consistent approach
RGO and HREC EO Focus Group. Discussion focused on: • Concurrent review • SSA redesign • Centralisation of aspects of research governance	RGOs and HREC EOs	• Clarify the policy position on concurrent review • Require the submission of a protocol or project plan • Explore the process and resource implications of centralising contract and indemnity review • Develop standard templates for budgets and protocols • Refine the LNR process to enable RGOs and HRECs to focus on the review and monitoring of higher risk research.
Research Leaders' Forum Discussion focused on: • Mutual Acceptance • Key Performance Indicators	Senior research leaders including Directors of Research, LHD executives responsible for Research, HREC Chairs, Senior Research Leaders in Universities, Private HRECs and representatives from key agencies such as Research Australia.	• Further develop the mutual acceptance model to include specialist HRECs such as paediatrics, justice health, and indigenous health • Include in the model provisions that a HREC decline or refer on an application that it does not have the expertise to review • Include in the model mechanisms of dispute resolution between HRECs and institutions and between HRECs and researchers • Enforce the KPIs of 60-day approval for

		HREC review and 30 days for SSAs through data reporting and communication with LHD CEs on underperformance. This measure links to timeliness as a measure of a good process and provides an incentive to review internal processes to ensure they are timely and efficient. • Implement mandatory requirement for concurrent review by institutions if requested by the researcher. • Mandate the requirement of a protocol/project plan to support well planned and considered research projects and clear communication of the methodology • Work with PHOs for improved documentation of requirements and availability of pre-submission review • Open discussions with the university and private sector to leverage existing training opportunities for researchers • Open discussions with the Guardianship Tribunal over extensive delays in review of clinical trials and the limited definition of clinical trials and high risk research

The strategy and attributes map underpin the reform process and will be used to evaluate any subsequent reforms and programs. The implemented plan is a high level overview of the work to be undertaken in the next 12-24 months.

1a. Initiative: Expansion of the SER model of HREC review in NSW							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 1/2	NSW PHOs' acceptance of University and private sector HREC review of multi-centre research in NSW	**1. MOU:** Establish MOUs between non-PHO entities with certified HRECs in NSW	Limited number of certified non-PHO HRECs in NSW; State exclusion of specific research	Reduction in duplicate reviews; Earlier start-up of research - delays reduced; Elimination of paperwork burden; Variation in processes reduced; Best practice standards; Human and monetary savings	MOU established	NHMRC proposed introduction of credentialed Clinical Trial HRECs; Clinical Trials Ready Initiative	Nov 14 - Dec 15
		2a. Policy Amendment: External entities, Insurance and Indemnity, Fees	Auditing of policy implementation; Influencing external / internal environments		Policies amended	Clinical Trials Jurisdictional Working Group Actions; Reform Initiative 6	
		2b. New Policy: Concurrent review, sponsor/research office communication, levels of review/exemption and roles and responsibilities					
		3. Standardised Forms, Templates and checklists: Update or create new forms, templates, checklists	Influencing external / internal environments		Standardised forms developed	ICT system - REGIS Project B; Clinical Trials Jurisdictional Working Group Actions - Governance, SOPs and contracts	
		4. Education and Training: Compile documentation on processes and responsibilities of researchers, sponsors, HRECs and institutions; Training needs analysis	Resources from each entity to compile information; Transition process		Guide and training toolkit	ICT system - REGIS Project B	
Consultation with stakeholders:							
Who: Certified non-PHO HRECs - Cancer Council NSW, UNSW, Charles Sturt University, University of Wollongong; NSW PHOs HRECs, NSW PHO Operational Managers/Directors of Research, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs), Researchers, TMF, Sponsors							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
This initiative is being undertaken under the current 'As-Is' process							

1b. Initiative: Expansion of the scope of the National Mutual Acceptance Scheme across Australia							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 1/2	All multi-centre research across Australia reviewed under NMA	**1. Amend MOU:** Definition change in MOU; Amend MOU in agreement with NMA States	Participation by WA, ACT, NT and Tas requires ICT system; Jurisdictional exclusions of specific research categories	Reduction in duplicate reviews; Earlier start-up of research - delays reduced; Elimination of paperwork burden; Variation in processes reduced; Best practice standards; Human and monetary savings	MOU amended and signed by each jurisdiction.	NHMRC proposed introduction of credentialed Clinical Trial HRECs; Clinical Trials Ready Initiative	Nov 14 - Dec 15
		2. Review Legislative Requirements: Identify jurisdictional specific requirements and compile an analysis of findings	Harmonisation of legislative reporting requirements		Analysis of findings	Reform Initiative 1a	
		3. Education and Training: Compile documentation on processes and responsibilities of researchers, sponsors, HRECs and institutions; Training needs analysis	Resources from each entity to compile information; Transition process		Guide and toolkit	ICT system - REGIS Project B	
Consultation with stakeholders:							
Who: NMA interstate jurisdictions, Researchers (state and national), interstate HRECs, TMF, NSW PHOs HRECs, NSW PHO Operational Managers, NSW Privacy Commissioner, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs)							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
This initiative is being undertaken under the current 'As-Is' process							

2. Initiative: Introduce a central allocation system for HREC review							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 3	Research applications are allocated to an HREC for review	**1. New policy:** Develop new policy, process, procedure and screening questionnaire	Procedure may change as a result of ICT solution	Streamlined and efficient process; Balanced distribution of applications to HRECs; Improvement in application quality	Policy, process and screening questionnaire developed	NHMRC proposed introduction of credentialed Clinical Trial HRECs; ICT system - REGIS Project B	Jan 16 - Jul 16
		2. Establish central resource	Resources	Central contact point and case management of projects	Central contact established	ICT system - REGIS Project B	
		3. Education and Training: New SOPs; Training needs analysis	Procedure may change as a result of ICT solution; Change fatigue	Consistent application, Best practice standards, Accountability	New SOP and toolkit	Standardised forms - Initiative 1a; ICT system - REGIS Project B	
Consultation with stakeholders:							
Who: NSW PHOs HRECs, NSW PHO Operational Managers/Directors of Research, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs), Researchers, Universities, Sponsors							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
This initiative is being undertaken under the current 'As-Is' process							

3. Initiative: Reform the site specific assessment process							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 1/2	Site Specific Assessment process amended	**1a. Policy Amendment:** Amend policy to mandate project plan, roles and responsibilities; remove LNR SSA for single site studies	Resistance to change; Lack of champion support; Lack of process owner buy-in	Reduction in timeframes; Enabling research governance culture; Duplication reduced	Policy amended	Reform Initiatives 1a, 1b; Clinical Trials Jurisdictional Working Group Actions - Governance, SOPs and contracts; NHMRC Clinical Trials Ready Initiative	Nov 14 - Dec 15
		1b. New Policy: Develop risk assessment process; Link with feasibility assessment and local signoff; Review utility of governance applications (LNR SSA and AR) in multi-centre research and escalation and dispute resolution process			New policy created		
		2. Forms: Simplify SSA form			SSA form simplified	ICT system - REGIS Project B	
		3. Education and Training: Compile documentation on processes and responsibilities of researchers, sponsors, HRECs and institutions; Training needs analysis	Transition process	Consistent application; Best practice standards, Accountability	Guide and toolkit	ICT system - REGIS Project B	
Consultation with stakeholders:							
Who: NSW PHOs HRECs, NSW PHO Operational Managers/Directors of Research, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs), Researchers, Sponsors							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
Some elements will be unique to NSW							

4. Initiative: Develop, Implement and establish agreed performance measures and minimum standards across a number of domains including throughput, timeliness, quality (of submission and review)							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 2/3	Performance and monitoring measures agreed, standards defined	**1. New Policy:** New policy on performance measures - 60days and 30days	Embedding research KPIs; Lack of Executive support; Data standards; Validation / data quality audits	Agreed comparable metrics; Standards defined; Accountability, Transparency	Performance metrics agreed; Standards defined	ICT system - REGIS Project B; Clinical Trials Jurisdictional Working Group Actions - IT Metrics and Interoperability	Jan 15 - Dec 15
		2. New Monitoring measures: Identify new monitoring measures to inform throughput, quality of submission and review					
		3. Education and Training: Compile documentation on processes; Training needs analysis	Transition process		Guide and toolkit		
Consultation with stakeholders:							
Who: NSW PHOs HRECs, NSW PHO Operational Managers/Directors of Research, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs), Researchers, Sponsors							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
Measures are based on current 'As-Is' process							

5. Initiative: Central Coordination - Governance Tasks							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 3	Governance tasks coordinated centrally	**1. Agreements:** Provide advice on CTRAs, insurance and indemnity and external entity agreements centrally	Influencing external / internal environments	Improved timeframes for authorisation	Central process established	Clinical Trials Jurisdictional Working Group Actions - Governance, SOPs and contracts; Reform Initiative 3	Jan 16 - Jul 16
		2. Establish central process: Identify elements for central review; Identify differences in site requirements					
Consultation with stakeholders:							
Who: NSW PHO Operational Managers/Directors of Research, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs), Researchers, Sponsors							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
Resistance to organisational wide transformation							

6.Initiative: University sector engagement							
Activity	**Outcomes**	**Actions**	**Challenges**	**Benefits**	**Performance indicator**	**Dependencies**	**Time frame**
Stage 1/2	Improved engagement with Universities	**1. Stakeholder engagement plan:** Establish relations with Universities **2. Progress Initiative 1a:** Cooperation to achieve good research practice standards	Managing expectations; Lack of champion support; Influencing external / internal environments	Gain trust; Greater sustainability	Plan established and implemented; Reform Initiative 1a implemented	Reform Initiative 1a, 1b	Nov 14 - Dec 15
Consultation with stakeholders:							
Who: NSW PHO HRECs, Certified non-PHO HRECs, NSW PHO Operational Managers/Directors of Research, Research Office personnel (Executive Officers, Research Governance Officers - EOs, RGOs), Researchers, Universities, Sponsors							
How: Consultation via workshop, focus group, t/c, email							
Risks:							
University research strategy - Alignment of values and motivations							