

Health and Medical Research Governance Project

Reform of the research pre-approval process

Discussion Paper

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NSW Ministry of Health, Office for Health and Medical Research

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Introduction

This **Discussion Paper** outlines a number of options for reform of the research pre-approval process in NSW. The reform options are not exhaustive and further suggestions of options, evidence and performance indicators are sought during the survey and in future consultation processes. The reform options outlined aim to deliver the highest business value to the users of the system and it is acknowledged that the needs of users will differ between stakeholders. This Discussion Paper is not intended to be internally consistent and presents options that may appear conflicting. The intention is to generate discussion and develop potential solutions to enable faster approval of research activities whilst ensuring high quality applications and review. Options are discrete, however there are relationships and interdependencies with other proposed reforms that will need to be considered in the solution design process. The Office for Health and Medical Research (OHMR) is aware of the National context of ethical and governance review and developments Federally and Interstate, but is committed to meeting the recommendations of the NSW Health and Medical Research Strategic Review (2012) and delivering value to stakeholders within NSW.

The term 'governance' is used throughout this paper as the more familiar term for institutional review or Site Specific Assessment (SSA). From a broader perspective, it is noted that ethics approval forms part of the overall governance framework that ensures the compliance, accountability and transparency of research activity at a site.

The purpose of this Discussion Paper is to identify the most significant barriers to timely, efficient review and to brainstorm options to deliver improved timeframes at the Human Research Ethics Committee (HREC) and research governance level. The paper opens a discussion on the challenges and opportunities associated with implementation and places importance on developing a consistent and transparent approach to performance measures of process timeliness and quality of both application submission and the substantive review.

Your feedback is sought on proposed reform initiatives outlined in this paper and the survey will ask you to consider options in terms of priority, value returned, feasibility and impact. They cover a number of areas including policy, structural and process reform. Some reform options are straightforward while others require further exploration and the details are not determined at this early stage. Your additional suggestions of areas that need improvements and potential solutions can be included in the free text comment boxes in the survey. There will be further opportunities for consultation and feedback as the reform options are refined.

The survey requests identified and potentially identifiable information, the purpose of which is to highlight the most important areas of reform to different stakeholder groups. OMHR may also contact you to clarify comments or to seek your consent to use quotes or comments in the final report. Only the OHMR team will have access to your identified responses for the purpose of data analysis and no identified or potentially identifiable information will be included in any report without your consent.

The survey consists of the discussion questions outlined in this paper and the options for reform outlined under each key option. You will be asked to prioritise each reform option as a must, should, could or won't do and there will be an opportunity to provide additional suggestions for reform and comment for each of the options.

The pre-approval process is complex with many interdependencies between policy, process and structure and it is understood that changes in policy will impact processes and supporting structures. Your feedback on the risks involved is also sought in the survey to help us understand the impact of the proposed reform.

Any queries during the completion of survey should be directed to: James Cokayne, OHMR, Research Ethics and Governance Unit, JCOKA@doh.health.nsw.gov.au or Ph: 9391 9920.

The Office for Health and Medical Research (OHMR) requests that institutions submit a single, compiled response on behalf of the institution. A single response will be received from each institution, although additional responses from individuals are encouraged.

Background

The OHMR has been established as part of the NSW Government Response to the NSW Health and Medical Research Strategic Review (2012) (NSW Strategic Review). This reform project is related to recommendations from two of the Response's 'Themes':

- (i) Theme 2 – Leadership in Clinical Trials, specifically, 2.3: Reducing barriers to clinical trials by faster start-up times
- (ii) Theme 11 – Improve NSW Health Research Administration, specifically, 11.1: Reform site-specific authorisation (research governance) processes

The Health and Medical Research Governance Project will concentrate on the 'pre-approval phase' of health and medical research, which primarily includes Ethical and Scientific Review (Ethics) and Site Authorisation (Governance).

The OHMR has initiated a project to review the requirements for a Research Ethics Governance and Information System (REGIS). It is critical that any information system supports best practice rather than dictating workflow. To deliver on the REGIS project timelines in 2015 it is essential that the pre-approval processes are working optimally prior to finalising design of the information system.

The NSW Government Health Policy Principles¹ will be used to prioritise reform options to create a system that:

- Is patient focused – access to better quality timely health care
- Has efficient and appropriate allocation of resources
- Has openness of governance and accountability of performance

Feedback from users of the process, including researchers, sponsors and support staff, describe the current environment as:

- Pockets of excellence but fragmented
- A system that is not well integrated and is difficult to share learning and successful initiatives
- Generally, slow, inefficient, and complex to navigate and administer
- Having requirements for submission that vary significantly and the information regarding what is required is not always readily available
- Having significant variation and duplication across the system with little clarity as to the value this adds to the quality of the process.
- Receiving applications that are often of poor quality and do not meet minimum requirements

The NSW Ministry of Health wishes to develop a pre-approval process that:

- Is efficient, agile and with minimal duplication
- Is accessible, with clear guidance and applied consistently
- Is transparent and measurable

How this paper was developed

The options outlined in this paper are informed by previous reports on system performance, academic literature, publications and survey data from stakeholders such as the Pharmaceutical Industry, and a review of international models and benchmarks.

The NSW Ministry of Health wishes to take a lateral and strategic approach to system reform that enhances the work done to date with the Single Ethical Review Model. Options for reform are not limited to clinical trials in recognition of the importance of timely approval for all types of research activities.

An Expert Reference Group was convened by OHMR to provide advice and input on the development of this discussion paper. A number of options were considered but excluded from this paper as they were considered to return low value to process improvement, or were not appropriate for achieving the project objectives of improving timeliness, reducing duplication and increasing consistency of the pre-approval process.

Option Excluded	Rationale For Exclusion
Reduction in the number of HRECs	An arbitrary reduction in the number of HRECs would not add value, it would need to be justified by an efficiency or quality gain
Optional, additional fee for priority review	Considered by the Expert Group as an inappropriate solution and is not supported by Industry representatives. The Expert Group preferred solutions that provided system wide improvement over selective priority processing
Increase trust between sponsors, RGO's and HREC Executive Officers	Reform solutions regarding clarity in the interaction between these stakeholders is addressed under Option 4: Reducing duplication and variation. The other reform initiatives around increasing trust between stakeholders were considered lower priority at this point and will be reconsidered when developing detailed solutions at future consultation meetings.
Accepted understanding of what is 'too long' with regards to approval timeframes	The intention of this reform is captured through agreed performance indicators

Feedback on the discussion paper, survey and consultation process was sought from the Chief Executives of Local Health Districts and incorporated into this paper prior to distribution.

Project Timeframes

The project will be undertaken in five phases with multiple points for consultation and testing of solutions.



Why Timeliness Matters

Slow start up times are frequently referenced by clinical trial sponsors, collaborative research groups and researchers as the single most important factor as to why Australia is no longer an attractive option for commercially sponsored international, multi-centre clinical trials. This loss of competitive edge has a flow on effect to the macro economy as well as the ability for patients in NSW to access emerging therapies.

For Local Health Districts, timeliness is critical for providing patients with access to novel therapies, creating a culture that values inquiry and innovation and in turn attracting and retaining staff. Clinicians involved in research are more likely to be evidence literate and promote best practice, evidence based care. This is an approach that benefits patients directly and the health system generally. From a management perspective, there is tangible value in ensuring that administrative resources are appropriately utilised with defects in the review process (including doubling handling, re-review, error correction) having a real time cost.

In the health research sector it is important that research is embedded in practice and that institutions undertake research activities that will lead to improvement in health and in the efficient delivery of health services. This in itself can lead to broad improvements in economic, health and social outcomes.

The emerging health research environment demands a service culture in addition to the existing quality review framework. A service culture encompasses accurate information, efficient, helpful, timely and responsive support. Stakeholders, including sponsors and LHDs need to implement a service culture in order to meet the common goal, to ensure patients have access to the highest quality, evidence based care¹.

The concept of timeliness should not be constrained to elapsed time but to also explore elements of consistency and efficiency. There is benefit to all stakeholders in the pre-approval review process in avoiding defects, rework and duplication.

Current System Performance and Benchmarks

The Australian Research Ethics Database (AU RED) is used statewide to capture approval times for HRECs and SSAs. It uses a start/stop clock to differentiate time in the hands of the HREC/RGO, researcher and total review times. AU RED data was reviewed for the 2012 calendar year. In 2012, 18 HRECs in Public Health Organisations reviewed research applications, and 13 of these Committees are certified under the NHMRC National Approach to Single Ethical Review.

HREC review

- 646 HREC applications were reviewed in 2012 across NSW HRECs in Public Health Organisations
- The average total review time for all HRECs, for all studies requiring full review was 77 days (33 – 165 days), and the HRECs with the two fastest approval timeframes also reviewed the least number of applications
- The average time in the hands of the HREC was 45 days (32-101 days) and the average time in the hands of the researcher was 32 days (0- 190 days)
- The data for some HRECs suggests that the clock was not stopped or started due to long total review times and zero (0) figures for stopped time in the hands of the researcher

Low and Negligible Risk (LNR) HREC review

- 668 LNR applications were reviewed in 2012 across NSW HRECs in Public Health Organisations
- The average total review time for all HRECs for LNR review was 32 days (5 - 58 days). The average time in the hands of the HREC was 24 days (6-46 days) and the average time in the hands of the researcher was 9 days (0 - 28 days)
- Many studies had zero (0) days stopped time, which may indicate that additional information is not often sought after submission

SSA review

- 1231 SSAs were reviewed in 2012 across NSW Public Health Organisations
- The average total review time for all SSAs was 36 days (3-66 days). The average time in the hands of the RGO was 23 days (3-58 days), and the average time in the hands of the researcher was 13 days (0-34 days)
- One LHD was excluded due to poor data quality

LNR SSA

- 843 LNR SSA applications were reviewed in 2012 across NSW Public Health Organisations
- The average total review time for LHDs for approval of LNR SSAs was 33 days (0-69 days). The average time in the hands of the RGO was 17 days (0-35 days), and the average time in the hands of the researcher was 18 days (0 - 45 days)
- Two LHDs were excluded due to poor data quality

National and International Benchmarks

Results from the 2013 Pharmaceutical Industry Council survey of research governance timelines show that on average, this review adds 49 days to study start up in Australia, however clarity in the start and end points is required for comparative analysis with AU RED. 2010 data cited in the report stated that 38% of respondents reported that it took more than 6 months to initiate a clinical trial and a further 25% said that it took between 4-6 months. It is unclear if the data is substantive or opinion based; but it demonstrates the substantial variation in the system.

The Clinical Trials Action Group recommends a combined 30-day best practice timeframe for both ethics and governance reviews², however it is unclear how this time frame was determined.

Victorian data for year-end 2012 for clinical trials only³ reports 69% of HREC approvals within 30 days, and 50% of Site Specific Assessments (SSAs) within 20 days. 77% of these trials were commercially sponsored, 87% were CTN studies.

The benchmark for review in Victoria is 30 days for HREC review, which at the end of 2012 was met by HRECs for 71% of clinical trials³

QLD has a 25-day clock for SSA approval by CEO or Delegate⁴ and a 60-Day clock for HREC Review⁵. Both clocks work the same as in NSW, which measure days in the hands of the HREC or RGO.

The UK has undergone major reform to its research governance framework following the 2010 Academy of Medical Sciences Report, and now operates under an entirely centralised model for ethics and governance review. The National Institute of Health Research (NIHR) provides funding to providers of NHS services on the condition that a 70-day benchmark to the recruitment of the first patient is met⁶. Therefore approval processes must be completed in less than 70 days.

Other European countries report time limits for ethics approval: Austria - 35 days, Belgium – 28 days, Bulgaria 35 days, France 35 days, and Latvia 30 days⁷.

Current NSW Policy Environment

NSW has a model of single ethical review for all types of research in contrast to other states (Victoria and Queensland) that limit the single ethical review model to clinical trials only. NSW has implemented a decentralised model where the investigator can select their HREC from a number of accredited lead committees with the exception of specialist areas of research such as research involving Aboriginal and Torres Strait Islander people and research conducted in the Justice Health System and research involving access to data sets managed by or on behalf of the NSW Ministry of Health. The model introduced in 2007 primarily focused on removing duplication of review in NSW.

An MOU was signed between NSW, QLD and Victoria in 2010 with the aim to further reduce duplication in clinical trials review with an implicit assumption that efficiency and improved time frames would follow. Whilst there is evidence for the reduction in duplication, there is little published in terms of system analysis or improvement against baseline. An absence of performance metrics and valid, robust data is a recurring theme in the literature and publically available reports.

Options for Reform

This paper presents options for reform that aim to deliver improved timeframes at the HREC and research governance level. The main emphasis of this Discussion Paper is to examine options for reform of the pre-approval phase of health and medical research, including challenges and opportunities associated with implementation. Reform initiatives span three aspects of the pre-approval review process:

- Structure
- Capacity and Processes
- Capability

Highest priority options for reform should deliver the highest business value in the shortest timeframe bearing in mind the constraints of the national framework. It is noted that the highest business value will vary by stakeholder group and your view is sought on what reforms will provide the best return for improving timeframes, efficiency and quality from your perspective.

Key questions when considering reform to the overall pre-approval system:

- What reform initiatives will deliver the most significant improvement in the shortest time?**
- What do you think the root cause(s) of delays are?**
- What additional data is required to identify the areas of key reform?**
- What might be appropriate performance measures? What data is required to monitor performance?**
- Do you have any examples of what works well?**
- What areas of policy or policy implementation should be revisited?**

Summary of Options

Structural Reform
Option 1. Explore the role of OHMR in system co-ordination, including central allocation of HREC Review and central management of appropriate governance functions
Option 2. Review fee structure and cost recovery model
Option 3. Establish clear and effective performance measures
Capacity and Process Reform
Option 4. Reduce duplication and variation in submission process between HRECs and LHDs for improved efficiency and consistency
Option 5. Internal process reform
Option 6. Reform information systems to support review process and performance evaluation
Capability Reform
Option 7. Ensure LHDs have the capability, workforce sustainability and skill mix required to deliver efficient, timely, high quality pre-approval review
Option 8. Ensure research personnel and sponsors have the capability and skill mix required to deliver efficient, timely, complete submissions

Structural Reform

Key questions when considering reform to the structure of the pre-approval system, including policy and system design:

1. What are the barriers to commencing research (e.g. role of University and non-PHO HRECs, NSW policy, researcher training, sponsor communication)?
2. What are the areas where previous policy implementation could be improved?
3. Does the system require large-scale restructure or re-engineering?
4. Has NEAF improved the process? What other options should be considered?
5. What aspects of the system could benefit from efficiencies of scale or centralisation?
6. What aspects of the system would work best in a decentralised model?
7. How should the private and university sector be considered? What reform is required for better integration?
8. Should any changes be made to the accreditation process for HRECS to be eligible to be part of centralised review? Should new criteria be introduced? If so what might be they be?
9. Does the current SSA/Governance review process meet its objective of providing institutions the information they need to make a decision to proceed (or not) with a study? Is it required? Can it be simplified? Is anything missing?

Structural Reform Options for Discussion

The options below discuss reforms to the major policy and governance structures of how research is reviewed in NSW. Some of these options are complex and not well developed. Some have many issues and potential barriers 'packed up' in them, particularly concerning centralisation. Please bear in mind the value that these reforms may, or may not add to improving timelines, consistency and quality of pre-approval review.

Option 1. Explore the role of OHMR in system co-ordination, including central allocation of HREC Review and central management of appropriate governance functions

Most pre-approval systems have elements of decentralised (local) and centralised (national) processes. The NSW Model is largely decentralised, however efficiencies may be gained by centralising some HREC functions such as providing a single point of submission and communication, standardised documentation and processes.

In early 2012, the UK National Health Service (NHS) implemented single governance review via the Health Research Authority and National Institute for Health Research. This process intends to reduce duplication in governance review and to be a single co-ordinating point to collect permissions.

Some aspects of the governance process that require particular expertise or are currently duplicated may be suited to a centralised model. This may include review of contracts and CTRAs, indemnity and insurance matters, External Entities agreements, arbitration, complaint handling and as an escalation point for dispute resolution.

What benefit will be delivered?

- Utilises existing HREC infrastructure, members and support, expertise is retained

- Co-ordinated, consistent application process
- Transparency in HRECs with efficient, timely review processes
- Provides an opportunity for HRECs to 'come up to speed' with the high performing HRECs
- Centralised co-ordination enables monitoring of consistency and data collection
- May encourage rationalisation of lead HRECs with low throughput, or may increase their throughput to a sustainable level
- Potentially provides a central mediator or arbitrator for issues or disagreements
- Develop clear, consistent guidelines on how specific poor performance or disputes will be handled
- Point of accountability where timelines can be measured centrally
- Central point for training, education, information exchange, developing and sharing best practice and successful initiatives
- Leverage limited research governance, risk and legal expertise
- Potentially remove duplication in SSA review
- Centralise review of clinical trial research agreements, material transfer agreements and contracts which will ensure consistency in advice
- Create a stable, sustainable point of expertise
- Benchmark approval time for governance reviews

Challenges

- Will require changes to HREC local procedure and documentation to ensure consistent documentation application process
- Investigators will no longer have the option to choose
- Will require investment in technology to enable to review and communication process
- Additional layer of accountability for HRECs to central co-ordinating body (system co-ordinator) who will monitor performance against benchmarks
- Will require change management plan for HRECs and researchers
- There may be significant lead time due to consultation, process and documentation development
- Adds in an additional administrative layer
- Potential loss of autonomy to institutions to negotiate contracts (excluding budgets)
- Tasks such as evaluating capacity and capability of the site and budget requirements will be difficult to do meaningfully in a centralised model
- Lack of knowledge centrally of local investigators, politics and resolution mechanisms
- Significant departure from current process that will require extensive consultation and process engineering
- Limited knowledge transfer when expertise is centralised
- Clear, consistent guidelines on how specific poor performance or disputes will be handled is critical

Options for reform

A) HREC System Co-ordination

- Establish the central co-ordinating body through OHMR or as an independent agency that is responsible for agreed aspects of single ethical and governance review
- OHMR to act as the central system co-ordinator, allocating applications to HRECs for review
- Expand mutual acceptance model to all multicentre research, not just clinical trials

B) Governance System Co-ordination

- Matrix of governance functions developed, current processes, anomalies and duplication to be identified prior to consultation on what may be appropriate to centralise
- 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

- Central agency/OHMR may act as a point of advice, dispute resolution and support for RGOs looking to improve their processes
- 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, ideally this 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

Current performance measures

- HREC review timeframes are captured in AU RED standard reports based on the 60 day clock for NEAF approvals, 30 days for LNRs
- No current benchmark for governance reviews

Proposed performance measures

- Time to approval from submission to co-ordinating body
- 20 – 30 day clock from submission as used in other jurisdictions for SSA's

Stakeholders

NSW Ministry of Health, LHDs, HREC members, Ethics Officers, local researchers, sponsors.

Comments

Most systems have dual component elements of decentralised (local) and centralised (national) processes. The UK is moving largely to a centralised co-ordination process (Health Research Authority) and there is performance data from the National Research Ethics Service to indicate that this is improving timeframes for HREC review. However, other countries have demonstrated shorter time frames within a decentralised approach. Therefore it is unclear exactly what value the structure itself lends to improved timeframes in the UK, as it is too early to draw conclusions from centralised research governance review data. Victoria and Queensland also have centralised their HREC submission process.

Other regulatory models such as environmental regulation are increasingly moving to decentralised models and less top down approaches. Methods such as education, capacity building and behavioural change models and incentives are used to encourage the desired actions and behaviours. Environmental regulators are spending less resource policing the system to catch out the minority offenders and more resources supporting companies to be compliant and building good environmental governance into their culture (Rand Europe).

Option 2. Review fee structure and HREC member payment

Resourcing has been cited as a barrier to extended approval time frames and options can be considered for improving resourcing, cost recovery and payment for priority review. An additional sense of accountability for the service provider is introduced in a full fee for service model. The fee structure and performance of private HRECs may be considered in this model.

The volunteer nature of HREC members has also been raised as barrier, in that members are limited in the time available for HREC related activities. What is the role of remuneration in improving review times?

What benefit will be delivered?

- Potentially additional revenue to LHDs
- Improved engagement and accountability from HREC members as they are remunerated for performing a service

- Additional funds for resourcing research offices
- Introduce additional accountability for the timeliness and quality of service

Challenges

- HRECs and Institutions will be held to the timelines by their customers
- Costs for non-sponsored research may increase dramatically
- Change of revenue streams to LHDs through changing fee structure and impact of centralised allocation
- May encourage 'forum shopping' for the most cost effective jurisdiction
- High fees or full cost recovery are likely to impact competitiveness
- Who pays? Where does the money come from?

Options for reform

- Payment of HREC members (sitting fee, agreed hourly rate or alternative model)
- Research Offices/HRECs to operate under a business unit model, including retention of revenue and accountability for profit and loss
- Undertake activity based costing analysis to determine fee structure
- Develop state wide fee structure consistent with other jurisdictions and private HRECs
- Allow institution and public health organisations to determine their own fee structures
- Introduction of a 'performance payment' or additional payment from OHMR to Institutions/HRECs that meet or exceed performance measures

Current performance measures

- Individual LHDs may have budget targets for their HREC/Governance cost centres, however these arrangements vary across NSW

Proposed performance measures

- Profit and Loss, performance against other metrics including throughput timeframes

Stakeholders

NSW Ministry of Health, LHDs, HREC members, Ethics Officers, local researchers, sponsors.

Comments

None

Option 3. Establish clear and effective performance measures

The review of the literature and publically available documentation demonstrated a consistent absence of robust data around HREC and RGO performance. Many articles provided case studies or analysed a small number of process examples. Although many issues are recurrent, there is little available that identifies root causes of delays or quantifies the location, cause or extent of delays. The major reviews and reports also appear to be based on consultation and opinion. It is difficult to paint a clear picture of the current system performance, particularly for governance review due to different approaches to data entry and data quality. Performance measures and robust data support decision-making and allow monitoring of performance, including the opportunity to identify and resolve problems early.

There is lack of common agreement on what is a 'good' review process and how it might be measured.

What benefit will be delivered?

- Robust, accurate baseline data from which improvement can be measured

- Mechanism for ongoing performance evaluation and management
- Improved transparency through published, identified performance against targets
- Accurate data to enable decision making
- Accurate data will better inform resourcing requirements

Challenges

- Performance measures previously subject to resistance
- Little consequences currently for failure to meet metrics, there is a need to establish where accountability should lie
- Will require translation to position descriptions and to performance management frameworks to ensure individual accountability
- Difficult to enforce benchmark time frames without linkages to incentives/disincentives

Options for reform

- 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
- Agreed, consistently applied start and finish point for timeframe measurement
- Investigate how performance metrics are used interstate with a view to any metrics being nationally consistent wherever possible
- Integrate collection of performance data within business processes
- Publish identified yearly performance and trend data: a format similar to the Radiotherapy Management Information System format may be appropriate
- IT system be designed to effectively capture metrics
- Implement a benchmark turnaround time for governance reviews

Current performance measures

- 60 days maximum for HREC approval of full applications in the hands of the HREC (NHMRC certification standards)

Proposed performance measures

- Implementation of agreed performance measures
- Embedding of measures in accreditation requirements for HRECs

Stakeholders

LHDs, research governance and HREC officers, NSW Ministry of Health.

Comments

Meta analysis in the Rand report indicated that uptake is low in encouragement based systems and that clear, enforceable performance metrics increase compliance.

Capacity and Process Reform

Key questions when considering the current system and capacity as well as future demands:

10. What data do you use to identify (i) how well processes work, and (ii) delays and bottlenecks?
11. What systems, processes or local initiatives have you encountered (or implemented) that work well or make the pre-approval process user friendly?
12. What processes are highly variable in your experience (e.g. concurrent review, use of documentation, different processes between sponsors)?
13. What aspects of NSW policy require amendment (e.g. fee policy, external entities agreement)?
14. For HRECs, RGOs and Public Health Institutions: How do you make sure your internal processes are timely and efficient?
15. What processes work well in your institution?

Capacity and process reform options for discussion

This section discussions opportunity to improve pre-approval processes at a system wide level and within institutions. It seeks feedback on where additional capacity is required and where processes may benefit from simplification or re-engineering. The reduction of waste through duplication is also a focus as is improving clear guidance process requirements and consistency in the application of processes.

Option 4. Reduce duplication and variation in submission process between HRECs and LHDs for improved efficiency and consistency

Variation in processes between HRECs and institutions creates significant additional workload for researchers of multi-centre studies, particularly where the differences are administrative rather than substantive. Although there are notable examples of where variation is required, the implementation of standardised documentation saves rework and duplication.

There is also variation in availability of advice, guidance and documentation with feedback being that many institutions have 'unwritten rules' for submission that are not clearly documented. Websites are not always maintained with the current documentation and there is variation in procedure from published Standard Operating Procedures (SOP). There is also variation in how low risk research activities are approached, their requirements and review processes. Researchers seek clear guidance on what does and does not require HRECs review – e.g. service evaluation activities.

What benefit will be delivered?

- Standardised process and documentation to the extent possible will lead to less confusion for applicants, HREC officers and HREC members
- Available guidance, processes and forms for use by all parties will improve quality of applications and speed of approvals
- Provide clarity on what activity needs to be reviewed and the expected time frames
- Reduce workloads for RGOs and HRECs
- Review level and submission requirements will be in proportion to risk

Challenges

- Require change management strategy for LHDs
- Achieving buy in from institutions to amend their processes and documentation

- Application of ‘proportionate risk’ is difficult, as it is a soft concept and difficult to create an exhaustive register of risk
- Risk that some studies that need HREC approval may not apply for it, however there are safeguards through explicit policy on what might be exempt and through the publication process

Options for reform

- Review the use of NEAF if it does not provide all the information HRECs require
- 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
- Implement use of existing standardised HoMER master consent documentation as a policy directive/condition of HREC accreditation in centralised allocation model
- Mechanisms to enforce requirement to accept approved documentation including approved participant information sheets and consent forms
- Amend NSW Policy to allow acceptance of HREC approval from any HoMER accredited HREC, including private HRECs such as Bellberry and issue clear guidance on what approvals can be accepted by NSW LHDs and PHOs
- Provide a clear statement of policy position of concurrent review of SSA and HREC application, which is currently at institutional discretion and make publically available which LHDs do or do not undertake concurrent review
- Introduce model of proportionate risk, where by level of completeness for review to commence should be proportionate to the risk involved in the proposal. E.g. missing signatures should not preclude a low risk SSA or HREC proposal from review
- OHMR to provide a clearer statement on levels of review (full, LNR etc.) and what activities are may be exempt from review, e.g. evaluation
- Develop a more efficient mode of administration for LNR HREC and SSA applications. LNR application administration is cumbersome and time consuming for researchers and administrators
- HREC Executive Officers and RGOs should be given authority to discuss matters with sponsors. This interaction is not prohibited in any guidelines or policy and requires clarification

Current performance measures

- No measure of variation in process

Proposed performance measures

- Compliance with standardised documentation – process audit
- Feedback from end users

Stakeholders

RGOs and HREC officers, LHDs, HREC members, NSW Ministry of Health.

Comments

Option 5. Internal Process Reform

Many RGOs and HREC Executive Officers have cited long, complex processes as a contributor to protracted pre-approval review time frames. Review of internal processes, process mapping and re-engineering provides an opportunity for improved efficiency and reduced complexity. Re-engineering may occur at the policy/operation procedure level as well as at an institutional level to identify bottlenecks, waste and develop best practice administrative procedures. This feedback can be integrated into the overarching policy, process and structural frameworks.

What benefit will be delivered?

- Establish evidence as to where the delays actually occur, maps the 'as is' situation
- Building data collection and performance metrics into workflow
- Opportunity to develop and implement best practice from a business process perspective
- Ensure appropriate allocation and use of resources or work around resource constraints
- Provide the opportunity to determine the average or median process timeframe from which informed benchmarks can be established
- Develop the best practice workflow and business process requirements for database/data management systems

Challenges

- Requires significant commitment from LHDs to process re-engineering
- Availability of Business Process Services expertise
- Cost of external services
- Research support staff are often resistant to process change
- Technology is a known barrier and may create a two-step process. The 'as is' will need to be mapped, then map most efficient pathway with AU RED followed mapping the ideal 'to be' scenario

Options for reform

- Establish best practice in business processes and standard operating procedures for Research Governance Offices, HREC Executive Officers and researchers
- Audit current of ethics and governance processes and practices against NSW standard operating procedures to identify areas of excellence and opportunities for improvement
- Audit of current compliance with mandatory NSW Health Policy Directives related to research
- Review UK experience on process improvements methods for research offices to objectively identify bottlenecks, reduce duplication and improve workflow

Current performance measures

- 60 days for HREC approval
- Internal performance measures

Proposed performance measures

- Amended timeframe measures for HREC review
- Introduce time frame measure for governance review
- Introduce additional customer satisfaction measures such as 360 degree feedback or survey after approval to assess quality of the process from an end user perspective

Stakeholders

LHDs, RGO and HREC officers, HREC members, researchers.

Comments

Option 6. Reform information systems to support review process and performance evaluation

The current system for managing the NSW ethical review model, AU RED is currently under review as part of the REGIS project. Any future system will be designed to meet the management and reporting needs of stakeholders, provide transparency to the process and as a means of collecting performance data. It is acknowledged that technology should support best practice systems and process rather than processes being designed to meet system requirements.

What benefit will be delivered?

- Information technology platform that supports best practice business processes
- Data will be available to assess performance metrics at an institutional, HREC and State level
- Improved workflow
- Improved transparency for applicants
- Provide a comprehensive research management platform
- Facilitate ongoing study monitoring
- Potential to deliver fully integrated single point of entry for study approval and management

Challenges

- A change management strategy will be critical and will need to cover education requirements of end users submitters
- Longer lead time to implementation for procurement, process mapping, testing and implementation May require LHDs to move from their existing systems
- Need clarity on the purpose of the system and what users can expect from it in terms of performance reporting.

Options for reform

- Information systems to provide customised reporting to end users (researchers and research offices)
- Information systems to be used to collect data for performance monitoring purposes
- Integrate the information system with existing systems such as TRIM or Oracle
- Provide real time data and proposal tracking for all stakeholders
- Information system to include modules such as grants, publications, intellectual property management
- Information system to include post approval monitoring such as complaints, safety reporting, monitoring and progress reporting
- Information system to be used to track recruitment and study progress
- Integration of accounts receivable, payable and other financial data
- In the comments box in the survey, please indicate any additional features or capabilities you would like to see in a research ethics and governance information system

Current performance measures

- AU RED performance measured by compliance with data entry, data quality and user feedback

Proposed performance measures

To be determined by user and technical requirements

Stakeholders

NSW Ministry of Health, RGO and Ethics Officers, system users such as researchers.

Comments

This reform option links with the existing Research Ethics and Governance Information System (REGIS) project.

Capability Reform

Key Questions when considering what skills and capability is required for an efficient, effective pre-approval process:

16. What are the key skills and attributes required by RGOs and HREC Executive Officer to facilitate the ethics and governance approval process?
17. What are the key areas for improvement in capability for sponsors, research personnel and ethics/governance officers?
18. Should there be any change to the functions of the Research Governance Officer as outlined in GL2010_15? See Appendix A
19. Should there be any change to the functions of the Ethics Officer as outlined in GL2010_014 See Appendix B
20. What should LHD research management structures look like to support the future direction of ethics and governance review?

Capability Reform Options for Discussion

This section considers the current and required capability of the research management workforce to support a timely, efficient, high quality pre-approval process. It considers matters such as workforce sustainability, skill mix and competency of all system users.

Option 7. Ensure LHDs have the capability, workforce sustainability and skill mix required to deliver efficient, timely, high quality pre-approval review

The introduction of the multicentre review model and the concept of the Research Governance Officer in 2007 have changed the role and function of many research offices. This new function demanded new skills that did not become apparent until after the implementation of the model and the ability of LHDs to respond to changes in skill mix and capability is sometimes limited.

Staff attrition and the loss of corporate knowledge can have a major impact on the pre-approval process. The recruitment and training process can be long and the HREC and governance officer roles require skills developed on the job. Due to the variation in studies reviewed, developing all encompassing and comprehensive training is challenging and time consuming in what is often resource challenged areas. Turn over creates additional workload for other staff and processes inevitably slow down. The loss of corporate knowledge can also have major effects on the efficiency of review, particularly when vested in individuals. The rapid expansion of research governance as a role also means there are many new, inexperienced staff.

What benefit will be delivered?

- LHDs will be equipped with the right skill and attribute mix in their staff to meet the demands of a service driven, technical environment
- Right people doing the right job
- Avoid the service and knowledge gaps created when key people leave

- Knowledge transfer
- Maintain service level and timeliness with staff turnover

Challenges

- Recognition of a need to change at an organisational level
- LHDs may need to consider restructure, realignment or retraining of teams to achieve the required capability mix
- Attrition, loss of corporate and technical knowledge
- Potential retention of high performing staff
- Recognise the role senior and executive management have the authorisation process and the potential for delay
- Workforce sustainability is a challenging area for health as a whole, research is no exception
- Constraints of recruitment policies and funding

Options for reform

- Develop standard position descriptions, capability statements and selection criteria for RGOs and HREC Executive Officers
- Embed performance metrics in above position descriptions
- Develop benchmark staffing levels in relation to activity levels to inform resourcing requirements
- Change management strategy focused on the behavioural change required to move from a compliance to a service culture
- Explore strategies for retraining and retaining staff
- Training for senior and executive staff with research responsibility to understand their role and be provided with advice and support mechanisms (e.g. central agency, key contact at other LHD)
- Structured staff rotation/secondment opportunities, potentially across organisations or departments for improved knowledge transfer, professional developed and developing best practice
- Clear succession planning to ensure staff turn over does not cause major knowledge and skill gaps or result in lengthened time frames
- Priority recruitment and allow hand over time to limit process downtime and the time involved in skilling up new staff
- Training for new senior/executive staff with research responsibilities

Current performance measures

- Performance evaluation of a service is undertaken at an institutional level
- Staff turnover is often reflected in protracted approval times

Proposed performance measures

- Evidence that performance measures are embedded in the performance development process of all staff, including senior and executive staff.
- Maintenance of benchmark performance despite staff attrition

Stakeholders

LHDs, RGO and HREC Officers.

Comments

Option 8. Ensure research personnel and sponsors have the capability and skill mix required to deliver efficient, timely, complete submissions

The poor quality, incompleteness and fragmented nature of applications is often cited as a reason for longer time frames and as an argument against concurrent review due to the double handling of applications.

What benefit will be delivered?

- Improved quality of applications
- Reduced resubmission and rework rates
- Applicant understanding of the regulatory and policy environment, including their non-delegable obligations
- Improved process efficiency and removing double handling

Challenges

- Recognition of a need to change at an organisational level
- Engagement and uptake of training opportunities
- Required information not always available
- Researcher desire to 'get something in' for a closing date
- Many of the proposed reforms fall within the remit of institutions, researchers, sponsors and supervisors rather than OMHR making implementation challenging
- Capturing and skilling up infrequent, poorly engaged and 'one off' researchers is very difficult. It is a time consuming process that may deliver little value

Options for reform

- Define capability and skills required for research personnel and sponsors
- Improve capability of researchers, supervisors and HRECs to improve the quality of the research conducted in terms of content and design to minimise the amount of low value research
- Explore practical training options to equip researchers with required skills (e.g. induction meetings/information packs) to prepare applications that will be approved first time
- A system of central accreditation of researchers against minimum training requirements (eg evidence of GCP training for clinical trials)
- Compulsory e-learning completed through the research information management system

Current performance measures

- Some institutions require evidence of GCP training investigators, however there is no consistent approach

Proposed performance measures

- Increase in number of complete submissions received by HREC Executive Officers and RGOs.
- Decrease in time in the hands of the researcher
- Feedback from HREC Executive Officers and RGOs
- Compliance with submission guidance and requirements

Stakeholders

Researchers, sponsors, industry associations such as ARCS and Medicines Australia.

Comments

Appendix A - RGO 001: Research Governance Officer functions

- 1.1. Each NSW Public Health Organisation will assign at least one Research Governance Officer and inform the NSW Department of Health of their name and contact details.
- 1.2. The name and contact details of each Research Governance Officer and the facilities, locations and services covered by them will be made publicly available on the Public Health Organisation and Department of Health websites.
- 1.3. The Research Governance Officer will have reporting lines to the Public Health Organisation's Director of Research (or equivalent) or other suitable senior officer(s).
- 1.4. Responsibilities of Research Governance Officers will include, but not be limited to, the following:

Pre-authorisation

- a) Advising and liaising with investigators, sponsors and other stakeholders regarding the preparation of applications for site authorisation
- b) Managing the process of site authorisation
- c) Assessing applications for site authorisation
- d) Ensuring collection of appropriate fees for site authorisation

Post-authorisation

- a) Managing and reviewing amendments to authorised research projects
- b) Having an oversight of authorised research projects through review of annual and final site progress reports submitted by the Principal Investigator
- c) Managing complaints related to the conduct of authorised research projects
- d) Conducting or coordinating audits of research projects, where required

Other

- a) Preparing reports to regulatory bodies, as required
 - b) Communicating with a wide range of stakeholders in the research community by providing information, education and high level advice on research governance
 - c) Managing support personnel and participating in all aspects of their recruitment, selection, induction, continued mentoring, performance management and the assessment of educational opportunities
 - d) Maintaining records, including databases and filing systems
 - e) Developing and maintaining web-based information for investigators
 - f) Monitoring relevant regulatory and policy developments to ensure changes are incorporated into local policies and procedures
 - g) Participating in the development and implementation of best practice policy, procedures, and standardised systems within the Public Health Organisation and the NSW public health system
- 1.5. The Research Governance Officer will delegate tasks as appropriate.
 - 1.6. An orientation package, developed by the Public Health Organisation, will be provided to new Research Governance Officers. A template will be available from the Department of Health.

- 1.7. Research Governance Officers will be encouraged to attend workshops, seminars and conferences related to their role. Examples include roundtable forums hosted by the Department of Health and training in the use of AU RED.

NSW Health, "Operations Manual: Research Governance Officers GL2010_015" (2010)
<http://www.health.nsw.gov.au/policies/>

Appendix B - EO 001: HREC Executive Officer functions

- 1.1. Each HREC will have an Executive Officer whose primary role is to manage the business of, and provide high-level executive support to, the HREC, the HREC Executive Committee and any subcommittees.
- 1.2. The name and contact details of each Executive Officer will be made publicly available on the Public Health Organisation and Department of Health websites.
- 1.3. Responsibilities of Executive Officers will include, but not be limited to, the following:

Pre-approval

- a) Advising and assisting investigators in the submission of all applications to the HREC. This will necessitate a knowledge of state and national legislation, policies and guidelines related to human research
- b) Managing all aspects of the application for ethical and scientific review of human research
- c) Reviewing applications to the HREC to ensure all documentation is complete
- d) Ensuring collection of appropriate fees for HREC review

Post-approval

- a) Managing amendments to approved research projects
- b) Managing appeals and complaints
- c) Managing annual progress reports and final reports
- d) Ensuring collection of appropriate fees for post-approval HREC review

Other

- a) Managing the activities and records of the HREC, the HREC Executive Committee and subcommittees
- b) Preparing reports to regulatory bodies, as required
- c) Developing and implementing a continuing education program for the members of the HREC to ensure they are up to date with current legislation, policy directives, and guidelines pertaining to human research. This will also involve an assessment of external educational opportunities
- d) Managing support personnel and participating in all aspects of their recruitment, selection, induction, continued mentoring, performance management and the assessment of educational opportunities
- e) Maintaining records, including databases and filing systems
- f) Developing and maintaining web-based information for investigators
- g) Monitoring relevant regulatory and policy developments to ensure changes are incorporated into local HREC policies and procedures
- h) Participating in the development and implementation of best practice policy, procedures and standardised systems within the Public Health Organisation and the NSW public health system

- 1.4. The responsibilities of the HREC Executive Officer in relation to HREC meetings will include:
 - a) Publishing the schedule of HREC meetings;
 - b) Preparing the agenda;
 - c) Allocating lead reviewers (where this is the practice of the HREC);
 - d) Distributing agenda and papers;

- e) Inviting the coordinating Investigator and, where appropriate, supervisors/student liaison officer or clinical supervisor to attend meetings and making necessary arrangements;
- f) Preparing the venue;
- g) Recording apologies for absence prior to the meeting;
- h) Raising with the Chairperson any concern that a meeting may not be quorate;
- i) Recording attendance by members for the discussion of each application for ethical and scientific review;
- j) Advising the meeting as necessary on compliance with standard operating procedures;
- k) Preparing the minutes of the meeting for review and approval;
- l) Notifying investigators of decisions and taking other follow-up action as necessary; and
- m) Identifying expert reviewers as required

1.5. The Executive Officer will delegate tasks, as appropriate.

1.6. An orientation package, developed by the Public Health Organisation, will be provided to new Executive Officers.

1.7. Executive Officers will be encouraged to attend workshops, seminars and conferences related to their role. Examples include roundtable forums hosted by the Department of Health and training in the use of AU RED.

NSW Health, "Operations Manual Human Research Ethics Committee Executive Officers GL2010_014" (2010) <http://www.health.nsw.gov.au/policies/>

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