Melbourne Academic Centre for Health

Monash Partners ACADEMIC HEALTH SCIENCE CENTRE

Western Alliance

VICTORIAN RESEARCH GOVERNANCE STREAMLINING

PHASE 1

DISCUSSION PAPER

CLINICAL TRIALS

Executive Summary

Research governance is essential to ensure the risks associated with human research are adequately mitigated. Good research governance will make sure that research protocols have been reviewed for their scientific merit, provisions are in place for them to be carried out with appropriate oversight by suitably qualified investigators, that they and their institutions are protected against potential adverse outcomes via suitable legal contingencies, and that there is the ethical regard for voluntary participants and use of community resources. Currently amidst a pandemic, the world awaits results of clinical trials and the efficiency and effectiveness of clinical research governance processes is more relevant than ever before.

What is required of researchers from individual institutions varies significantly. The processes used to meet obligations in clinical research governance also varies. Some of these differences have come about due to fundament site differences, but there are considerably more similarities between sites than differences. Differences in requirements and processes presents researchers with a complex navigation task that they must overcome if they wish to conduct cross-sector research. There is a need to harmonise requirements and, taking into account site differences, harmonise research governance processes so that they are less prohibitive to valuable translational research.

An environmental scan has identified issues creating the greatest friction in research governance approval processes. Areas in need of harmonisation have been divided into two phases:

1. **Phase 1 - Clinical Trials Governance Streamlining**
2. **Phase 2 – Non Clinical Trials and Quality Assurance Governance Streamlining**

Phase 1 topics include:

- researcher credentialing
- complex administrative requirements and insufficient access to skilled labour
- lack of research resources in smaller rural sites
- obtaining signatures
- wide variation in staffing, skills, knowledge and training, and management roles
- information in handbooks, standard operating procedures (SOPs) and websites
- access to and functionality of IT platforms
- Supporting Department fees

The Victorian Research Governance Working Group is now tasked with considering the current landscape and how best to make Phase 1 reforms for high value gains that can be maintain well beyond their implementation. Reforms will need to align with the National Clinical Trials Governance Framework (NCTGF) and relevant revisions of the *National Statement on Ethical Conduct in Human Research* (*National Statement*), as well as the *Australian Code for the Responsible Conduct of Research* (*The Code*).

Introduction

More than ever before, the world's attention is on clinical trials. Experts and non-experts alike are questioning, and looking for assurance, that trials are being conducted in a way that produces meaningful results leading to effective treatments and preventative medicines, which will allow us to return to our daily lives relatively free of fear of disease (and unwanted side effects). We all want to know that this will be expedited without compromising safety. Good clinical research governance has never been more important than now. Institutions have an obligation to encourage and support responsible research conduct.[1]

Clinical research governance plays a crucial role in mitigating risks associated with human research. With the world's attention on clinical trials, and a never before equalled, wide-spread sense of urgency, there is an imperative for health institutions, more than ever, to actively employ research governance processes that are as effective and efficient as possible, ensuring risks are adequately managed, while facilitating the development of urgently needed treatments and preventative medicines. Whilst there is an urgency to ensure inefficient research governance processes don't unnecessarily delay progress that will bring an end to the COVID-19 pandemic, this is equally applicable to many other diseases that have debilitating effects, and will continue to do so beyond the current pandemic.

A persistent barrier to more streamlined and efficient research governance is the lack of harmonisation in the manner in which it is achieved amongst individual institutions. For multicentre studies it is well understood that, whilst ethical approval may now be achieved through a centralised process using standardised documentation, this is not true for research governance. There are over eighty public health services across Victoria as well as myriad private services, none of which appear to have harmonised governance processes. Whilst there may be legitimate reasons for some local requirements that differ between these organisations, there are far more similarities between them. If each organisation has their own slight variation in research governance processes, there is instant disparity that is complex to navigate and is recognised as a barrier that discourages valuable cross-sector research. A more global approach to identifying the opportunities to harmonise practices is urgently needed. However, it is more complex than simply publishing a standard set of SOPs, as institutions have existing work practices and SOPs that can't be readily replaced en bloc. Nevertheless, there is a discrete opportunity to undertake a body of work to identify the SOPs in use and perform an evaluation of how these differ across institutions.

Currently, there are a number of collaborative fora that are well placed to lead this work, with the best placed one being the Hospital Research Managers Forum (HRMF). This network has a history of effectively workshopping common problems to identify practical solutions. It is able to facilitate a state-wide approach to process change that will ensure consistency. It is also able to escalate ideas for potential system changes to more senior levels, such as the Hospital Research Directors Forum (HRDF), the Coordinating Office for Clinical Trial Research and the National Health and Medical Research Council (NHMRC), for consideration. It must be recognised, however, that members of both hospital fora are

continually stretched to capacity in their daily activities, and therefore unable to dedicate the consistent effort required to ensure that crucial changes take place in an efficient timeframe. Hence, dedicated resources, will be needed for meaningful progress to occur.

To date, a short-life working group and project officer have been allocated to identify problem areas, consider possible solutions and construct a proposal for reform. Interviews with groups and individuals that have oversight of research governance have provided insights into current practice and a sense of appetite for reforms that would result in more streamlined administrative processes and harmonisation of governance requirements across the Victorian health sector. Areas that create the greatest friction have been identified and the working group is now tasked with developing workable solutions that will relieve pain points and significantly improve efficiency. Resourcing will need to extend beyond ideation to effect tangible improvements through implementation, particularly as the COVID-19 pandemic extends beyond 2020.

An environmental scan has been performed across Victorian Health services to scope current research governance practice, understand existing and potential enablers and barriers to process efficiency, and identify common issues in the clinical research governance function that are in need of reform. Interviews were conducted with key stakeholders and consideration has been given to the experiences of researchers and Research Governance Office (RGO) staff.

The National Clinical Trials Governance Framework (NCTGF)[2] was in development by the Australian Commission on Safety and Quality in Health Care during the Victorian clinical trials governance environmental scan. The National Health and Medical Research Council was also undertaking a revision of the *National Statement on Ethical Conduct in Human Research* (*National Statement*)[3], of which, *Section 5, Process of Research Governance and Ethical Review*, will also be of relevance. Neither were available for consideration in the development of this discussion paper. However, the Victorian Research Governance Working Group will need to ensure that its recommendations align with both the NCTGF and *National Statement* as well as *The Code*[1].

The working group task has been divided into two phases:

Phase 1 - Clinical Trials Governance Streamlining proposal, and

Phase 2 - Non Clinical Trial research and QA streamlining proposal.

Phase 2 will be the subject of a separate discussion paper, following completion of Phase 1.

Phase 1 - Clinical Trials Governance Streamlining

The table below lists the issues that have been identified and potential solutions to be considered for Phase 1 reforms:

Issue	Potential Solution
Researcher credentialing 1. Variability of minimum requirements for a person to be allowed to conduct research at a site e.g. related training and experience; GCP or equivalent certification; professional indemnity including the conduct of clinical trials. 2. A suitably qualified researcher is required to submit evidence of their credentials to each site they wish to conduct research at, duplicating submission processes.	1. a) Consensus to be reached via consultation between sites, or b) All sites adopt highest level of requirements currently accepted 2. Create a central 'Research Passport' repository that enables credentials to be securely accessed by all relevant sites.
Complex administrative requirements and insufficient access to skilled labour Navigating varied requirements across sites and staying abreast of changes in guidelines, codes, standards and legislation requires specialist attention	Adopt one or more of several models currently in use: a) RMH & Eastern Health - Clinical Trials Research Manager b) St Vincent's – Research Valet c) RCH – Plain Language Adviser d) Numerous sites – subcontract to CTA who allocate Ethics (and Governance) Submission Specialists
Lack of research resources in smaller rural sites This is prohibitive to local research, further limiting their ability to make meaningful improvements to already marginalised rural health services that provide care to vulnerable communities. Needed resources include equitable access to HREC review, independent peer review and Ethics Review Manager (ERM). Current informal arrangements between smaller rural services and larger regional sites place both services at risk.	1. Formalise current work-arounds that support smaller rural health services via larger regional services. 2. Establish a pool of peer reviewers 3. Business case for further resourcing
Obtaining signatures Disparity exists in mode of signature required or accepted on legal documents	All sites to accept verified e-signatures as a minimum, and consider transition to providing e-signatures over time.

Issue	Potential Solution
Staffing, skills, knowledge and training – wide variation, including in management roles 1. Variation and gaps in RGO skillset and ability to recognise potential resourcing and costing impacts to their institution 2. Infrastructure nuances between sites	Introduction of an RGO training module that explains the basic elements and purpose of the role and includes an essential supplemental unit explaining site specific infrastructure and nuances related to the RGO role
Information sources- Websites, handbooks and SOPs There is evidence of outdated SOPs and some inconsistencies between organisations that can create confusion, particularly for running studies across sites.	1. An initiative to re-write SOPs. 2. Institutional information sources to be systematically overhauled for accuracy and consistency via HRM.
IT platform functionality 1. Limited functionality persists, particularly reporting capabilities 2. Smaller rural sites do not have access to ERM	1. Established working groups to continue dialogue to resolve ongoing issues 2. VRGSWG to provide support to the ERM Research Office User Group
Supporting Department fees Fees vary, not only from site to site, but also within sites and there is little appetite to standardise fees.	Action to be considered at a later date, if warranted.

Discussion

Researcher credentialing

Researcher credentialing is aimed at ensuring research is conducted by suitably qualified individuals within their area of training and competency and in a manner consistent with Good Clinical Practice (GCP). Currently, recognised GCP courses vary from site to site. Prior to COVID-19, some insisted that GCP training was completed face-to-face, while other sites will accept any GCP certification. In addition to GCP, researchers must also complete mandatory training, required as part of hospital accreditation. A suggestion is to add an optional research-specific module to site online training. This might also include principles outlined in the *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Human Research*. Agreement is needed on minimum requirements.

In order to conduct multi-site research, a researcher must be credentialed at each site. Again, the COVID-19 pandemic has highlighted the need for economy of scale. In order to meet surge capacity, clinical staff have been transferred across hospitals and consideration has been given to recognition of prior completion of mandatory training modules. A similar approach could be applied to researcher credentials. A central repository would facilitate the process, as once a potential researcher has gathered essential documentation for credentialing, this would be uploaded to the repository (preferably ERM with added functionality). Following verification by the initial reviewing site, a 'Research Passport' would be transferable and accessible to all relevant sites. Ideally, the IT platform would be automated to send alerts to the researcher and to research sites ahead of expiries.

The HRMF is ideally placed to host discussions around acceptable requirements and implementation of a research passport. Representatives are currently part of the ERM Research Office User Group, which is able to include this functionality on its current list of items for attention.

Complex administrative requirements and insufficient access to skilled labour

The 'Scotland Model' of having a Clinical Trials Research Manager appointed in each hospital to coordinate administration of clinical trials has been promoted as having achieved noticeable efficiencies, particularly with feasibility negotiations and departmental sign-offs. It should be noted, however, that Scotland's centralised National Health Service acts as the hospital staff employer. This has obvious implications for funding and incentive.

In Victoria, hospitals are largely autonomous. However, there are a few similar models in use in Victorian hospitals. Both Eastern Health and the Royal Melbourne Hospital have a clinical trials manager who acts as the central contact and facilitates negotiations between pharma, the hospital, investigators and the Research Governance Office. Both sites attest to the efficiency of having a specialised role that eases the administrative burden on clinicians and research nurses, raises the standard of ethics and governance submissions and results in faster approvals.

There are other examples of roles employed to assist with specific administrative tasks associated with research. These include St Vincent's Hospital Research Valet who is available to assist with ethics and governance submission on a fee for service basis, and the Royal Children's Hospital Plain Language Adviser, who reviews and assists with writing participant information sheets. Another, which has been used widely is the Ethics (and Governance) Submission Specialist allocated to sites subcontracting to Cancer Trials Australia (CTA). Whilst they started out in Oncology trials, CTA have now expanded their service to other disciplines. Sites that have adopted a CTA specialist have all reported great advantage over other means of clinical trial administration. What these all have in common is the dedication of skilled staff who deal with the complex administrative processes of research routinely and therefore more far more efficiently.

Lack of research resources in smaller rural sites

While work-arounds have been established to support smaller rural health services via larger regional sites, the informal nature of arrangements, places rural and regional services at risk. A formalised relationship, e.g. larger regional hospitals adopting surrounding smaller hospitals as affiliates, would clarify processes and improve accessibility to services. Some of the smaller hospitals, such as Colac Area Health are just starting to find their feet in terms of research governance by outsourcing the RGO role. A serious investment is needed to support rural services and provide opportunities for local research.

Obtaining signatures

While individual sites may have various reasons for not providing E-signatures, there should be no reason not to accept verified E-signatures. An eventual transition to wider use of E-signatures will progress organically. Sites that wish to adopt E-signatures are able to consult with other sites that have already transitioned for guidance. Acceptance of E-signatures would allow investigators who are frequently off site to sign documents remotely from any location. Wider adoption of E-signature, including supporting departments, would significantly ease the administrative burden of tracking documents, physically distributing and collecting hardcopies for wet ink signature, and reduce avoidable delays experienced in obtaining governance approval.

Staffing, skills, knowledge and training – wide variation, including in management roles

A basic training module could be implemented to include essential elements of research governance. As there are nuances between sites and variation in infrastructure, it is important that RGOs have a good understanding of these aspects and are familiar enough with their own site infrastructure to be able to determine how research may be constrained and the impact of research projects on site resources. Thorough understanding of the purpose of research governance and how it needs to be managed specific to institutions is essential, as is building site processes into standard operating procedures for transparency.

IT platform functionality

As there have already been three separate working groups established to identify issues and improve the functionality of ERM, it will be within their remit to solve remaining issues. It is vital that the Research Office User Group maintain an open dialogue with the department and Technical Working Group and continue to work on resolving ongoing issues. The VRGSWG can offer support by highlighting ongoing issues requiring the most urgent attention. Reporting capabilities seems to be the main restrictive problem and needs to be resolved for sites to be able to complete NHMRC certification requirements and annual Victorian Health Complaints Commissioner reports. This functionality is also crucial for internal reporting.

It is also important to note that research is not necessarily discrete in each state. Therefore, a national interface is needed. This would also significantly improve Australia's reputation amongst big pharma and international investigators as a clinical research destination.

Information sources- Websites, handbooks and SOPs

Some assistance is needed to enable identification of inconsistencies, harmonisation of information and correction of misinformation so that researchers have access to uniform, reliable guidance at all sites. Published information must be updated as applicable changes occur to prevent confusion and misguidance. The Victorian Department of Health and Human Services *Research Governance and Site Specific Assessment Process and Practice*[4] will need to be replaced once reforms have taken place. Again, the HRMF is ideally placed to facilitate standardisation. However, RGO resources are frequently stretched to capacity. An initial investment of additional resourcing may need to be allocated to ensure that immediate broad-ranging inconsistencies are addressed promptly.

Supporting Department fees

There is little appetite to standardise fees. This is not necessarily considered a significant issue, as pharma companies are generally accepting fee estimates. Therefore, there is currently not much value to be gained from expending resources in this area. This could be reviewed at a later date via the HRMF. Note, standard costs associated with conducting clinical trials in Australia have been determined by the Independent Hospital Pricing Authority (IHPA).

Conclusion

In the Phase 1 initiative of streamlining clinical trial governance, the two most important areas for reform are making researcher credentials transferable and accessible across sites, and decoupling administrative tasks from research activity via employment of specialist research administration staff. Other significant gains could be made by formalising relationships between smaller rural and the larger regional sites providing them with resources, and defining the research governance role and upskilling RGO staff.

It is important to note that the Victorian Research Governance Streamlining Working Group recommendations will need to align with the National Clinical Trial Governance Framework recommendations and revised *National Statement* as well as *The Code*.

Appendix 1 - Interviewees

Institution	Interviewee
Alfred Health	Angela Henjak, Senior Manager, Office of Ethics & Research Governance Stephen Jane, Director, Research
Austin Health	Sianna Panagiotopoulos, Manager, Office for Research Lisa Pedro, Manager, Ethics and Research Governance
Barwon Health	Giuliana Fuscaldo, Joint Manager, Office for Research Lisa Fry, Joint Manager, Office for Research
Ballarat Health Services	Ashleigh Clarke, Manager, Research and Partnerships Diane Clingin, Manager, Ethics and Research Governance
Colac Area Health	Laura Alston, Research Ethics and Governance Coordinator Michael Field, Research Ethics and Governance Coordinator
Department of Jobs Precincts and Regions	Catherine Farrington, Systems Coordination, Coordinating Office for Clinical Trial Research
Eastern Health	David Taylor, Director of research and University Relations
East Grampians Health Services	Jaclyn Bishop, Research Governance Coordinator
Epworth HealthCare	Nik Zeps, Director of Research and Development
Latrobe Regional Hospital	Jhodie Duncan, Research Manager
Melbourne Academic Centre for Health	Michelle Iddles, Manager
Monash Health	Deborah Dell, Manager, Research Support Services & HREC
Monash Partners	Kurian Thomas, Clinical Research Facilitation
Royal Children's Hospital	Nitya Phillipson, Director of Research Operations
Royal Melbourne Hospital	Sarah Rickard, Manager Research Governance and Audit Margot Osinski, Project Team Lead, Research, Connecting Care Program – Parkville EMR Angela Watt, Director Research Governance and Ethics
Southwest Healthcare	Arti Mishra, Research Governance Officer Barbara Moll, Manager, Education, Research and Workforce Development
St Vincent's Hospital	Leanne Clinch, HREC Secretary Lily Woods, Senior Research Ethics and Governance Officer
Western Alliance	Drew Aras, Executive Officer

Appendix 2 – References

1. National Health and Medical Research Council, *Australian Code for the Responsible Conduct of Research* (2018)
2. Australian Commission on Safety and Quality in Health Care, *Clinical Trials Governance Framework* (2020)
3. National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research* (2007, updated 2018)
4. Victorian Department of Health and Human Services, *Research Governance and Site Specific Assessment Process and Practice* (2014)