December 2021

Research Governance Project Report

Phase 1: Problem Definition

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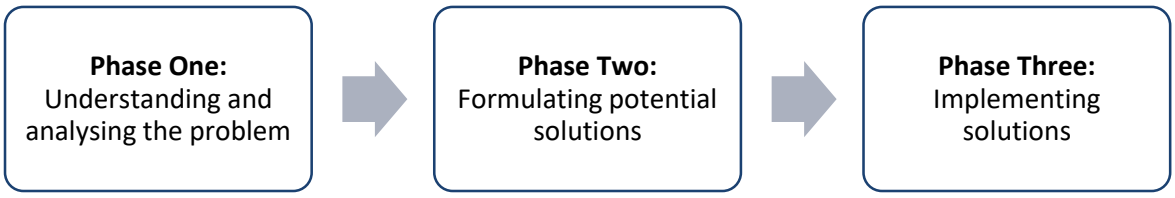
Project Background

Research is essential to the provision of safe, effective, and efficient healthcare. Evidence suggests that organisations participating in research have improved patient outcomes and lower mortality rates [1, 2, 3, 4]. Healthier populations contribute to stronger societies with positive economic growth. Additionally, research such as clinical trials attract commercial investment in local research, stimulate the economy and create jobs in the research sector including healthcare providers, universities, and research institutions [5]. Clinical trials also benefit society through facilitation of early access to interventions, enhancing the capability of health systems and connecting local researchers to the international research community [6].

Effective conduct and management of research requires a strong and proportional research governance framework. There are, however, concerns regarding the efficiency and capability of the existing research governance system [5, 6, 7]. Opportunities exist to streamline and strengthen the existing system to enhance the capacity and capability of public health organisations in NSW to further embed quality research into healthcare delivery and become an attractive destination for clinical trials.

The 'Research Governance Project' aims to strengthen and further develop NSW Research Governance infrastructure to facilitate high quality research undertaken efficiently and effectively through the following three (3) phases:



The project is led by Sydney Research (Sydney Local Health District (SLHD)), St Vincent's Hospital Sydney Limited (SVHS) and the NSW Office for Health and Medical Research (OHMR) and supported by the 'Project Manager (Embedding Quality Research)'.

The Embedding Quality Research (EQR) Steering Committee has oversight of the project. The EQR Steering Committee includes senior executives from 17 Local Health Districts and Specialty Networks, two (2) Advanced Health Research Translation Centres (AHRTCs), NSW Regional Health Partners, NSW Health Pathology, eHealth NSW, Cancer Institute NSW, Agency for Clinical Innovation and NSW OHMR. To ensure the timely delivery of project outputs and achievement of project outcomes, the EQR Steering Committee established the EQR Research Governance Expert Working Group to provide expert advice and guidance to the project. The Expert Working Group is comprised of five (5) metropolitan and regional Public Health Organisation (PHO) Research Directors.

This document provides a report of the findings from phase one (1) of the project which was focused on understanding and analysing the problem.

Methodology

The following methods were utilised to complete phase one (1) of the project.

- **Literature Review**
  A literature review was conducted covering both academic and grey literature related to the existing research governance systems in Australia and NSW.

- **Process Mapping**
  Process maps of how research governance is currently operationalised in NSW PHOs were also created based on current practice and policies:
  - Appendix one (1) presents the overall research governance processes of NSW PHOs at a high level.
  - Appendix two (2) presents the research governance workflows on the Research Ethics and Governance Information System (REGIS)
    (Note: this figure was created by the REGIS team at NSW OHMR).

- **Surveys**
  Anonymous surveys were conducted with Research Governance Office (RGO) staff and researchers across the NSW Health system. The surveys consisted of both quantitative and qualitative questions exploring the respondents' experience with the current research governance system and their views on areas where they believe improvements and / or reform are required and would be beneficial. 384 researchers and 55 RGO staff responded to the surveys. Partially completed surveys were included in the analysis to capture all contributions.

- **Individual Interviews with RGOs**
  Informal individual interviews were also conducted with RGO staff from ten (10) PHOs in the Sydney metropolitan region and four (4) in rural and regional NSW.

- **REGIS Data**
  Quantitative data from REGIS was obtained to further complement the qualitative data gathered through the other methods.

Findings

The following sections summarise key challenges experienced with the existing research governance processes as identified through the literature review and consultations with RGO staff and researchers. Each section concludes with recommending potential solutions to inform Phase two (2) of the project which will involve developing strategic solutions in collaboration with all relevant stakeholders including RGO staff, PHO Executives, NSW OHMR, researchers, AHRCTS, NSW Regional Health Partners and the Industry.

Apart from the challenges, this phase of the project also revealed the strength of the system to be its research community including RGO staff and researchers. Responses to the consultations revealed a highly engaged research community supportive of change and reform. Additionally, there have been multiple initiatives and projects initiated by the sector (including AHRTCs and NSW Regional Health Partners) to address some of the issues explored earlier in this report. These activities lay a strong

foundation for phase two (2) of the project to develop strategic solutions for the issues identified in this phase.

History of Research Governance

Understanding the context from which the current research governance system emerged, and the history of its evolution is essential to the accurate analysis of the identified issues and formulation of sustainable solutions. In the words of the philosopher, George Santayana, "those who do not remember the past are condemned to repeat it."

Institutions are accountable for research conducted at their site/s and must ensure compliance with all relevant ethical, scientific, and regulatory requirements. Additionally, institutions require research conducted at their site/s to be within acceptable levels of institutional risk and consistent with their strategic vision and objectives. Research governance is the framework through which these requirements are met.

Historically in Australia, the Human Research Ethics Committee (HREC) of each institution was responsible for both research ethics and research governance. This meant that multi-centre research projects required the submission of separate research ethics applications to each institutional HREC. Following complaints about the inefficiencies of duplicative ethical reviews, the Australian Health Ministers' Advisory Council (AHMAC) agreed to establish a national single-ethical review process through the Harmonisation of Multi-centre Ethical Review (HoMER) initiative. The National Health and Medical Research Council (NHMRC) was the facilitator of this initiative and developed a national system for single ethical review of human research in 2006 [8, 9, 10].

The National Certification Scheme for Institutional Ethical Review processes (NCS) was one of the tools utilised by the NHMRC in achieving this aim by providing assurance to stakeholders that policies, processes and procedures of an institution and its HREC comply with an agreed set of national standards. Institutions were also assured that a single ethical review would not replace local review of governance matters. The NCS was designed so that it is voluntary and excludes research governance matters to respect the institutions' autonomy in deciding as to whether research should be conducted at site/s within their jurisdiction [11]. Furthermore, the National Statement on Ethical Conduct in Human Research (2007) also reflected the separation between ethical and research governance reviews to support this arrangement.

In 2007, NSW instituted a single ethical review arrangement within the NSW public health system [10] through the creation of the Site Specific Assessment (SSA) process and as per Policy Directive (PD) 2007_043: *"Research – Authorisation of proposals to conduct research on humans within NSW public health system"*. This PD was later replaced by PD2010_056: "*Research - Authorisation to Commence Human Research in NSW Public Health Organisations"* in September 2010. The NHMRC published the Research Governance Handbook in December 2011.

The Research Governance Handbook acknowledged that the changes in roles and responsibilities of the various stakeholders may still require further refinement and provided guidance on best practice in the governance of multi-centre human research under the single ethical review model. The Clinical Trials Action Group's report in 2011 highlighted that research governance is still less

developed compared to research ethics and ambiguities remain in the roles and responsibilities of different parties [10].

In 2011, the 'Interstate Mutual Acceptance' arrangement was established between NSW, QLD and VIC to enable mutual acceptance of ethical review of multi-centre human research in public health organisations within those states [11, 12]. This arrangement was superseded by the National Mutual Acceptance (NMA) scheme in 2013 [11]. The NMA involves a Memorandum of Understanding signed by Australian state and territory health departments for the mutual acceptance of ethical review of multi-centre human research in public health organisations. Australian States and Territories gradually joined the NMA and from late 2020, all Australian States and Territories now participate in the scheme [13].

The AHMAC's vision in 2006 was that a single ethical review system coupled with local governance review would streamline approval of multi-centre human research. Instead, it became evident by 2011 that obtaining research ethics and governance approvals in Australia is becoming increasingly lengthy and has a high degree of variability between different sites [10]. Researchers expressed concern that the "advantages of a harmonised single ethical review process were undermined by the coexistence of a fragmented, complex and lengthy governance approval process" [14]. Similar concerns remain to this date as reflected in the findings of this project.

This history reveals that research governance was separated from research ethics to enable efficient authorisation of multi-centre human research. The SSA model was created to operationalise this new arrangement. The concept of research governance, however, has not been further developed since its introduction in Australia which has led to varying understandings of roles, responsibilities, requirements and processes. There have been no further updates to the NSW Health PD2010_056 or the NHMRC Research Governance Handbook since their publication a decade ago and at the infancy of research governance.

Recommended Potential Solution/s

1. Learning from this experience, this project recommends further developing the concept of research governance and establishing a 'Research Governance Framework' for NSW PHOs which clearly defines the roles and responsibilities of all relevant stakeholders including the institutions (hosting and / or sponsoring research), researchers and external sponsors. It is essential that the framework is dynamic and responsive to a rapidly changing research environment including other initiatives such as the National Clinical Trials Governance Framework and the potential establishment of a national health and medical research approvals platform (National One-Stop-Shop). Strategies must be put in place to continuously evaluate and improve the framework to ensure its clarity, adequacy and relevance over time.

Site Specific Assessment (SSA)

As mentioned earlier, the existing SSA model was designed to operationalise the single ethical review arrangement. The current process (appendix 1) requires the submission of the research ethics application prior to the generation of the SSA application form on REGIS. This arrangement encourages the researchers to focus on their research ethics applications initially while considering their research governance applications a secondary step in the process. The interviews with RGO

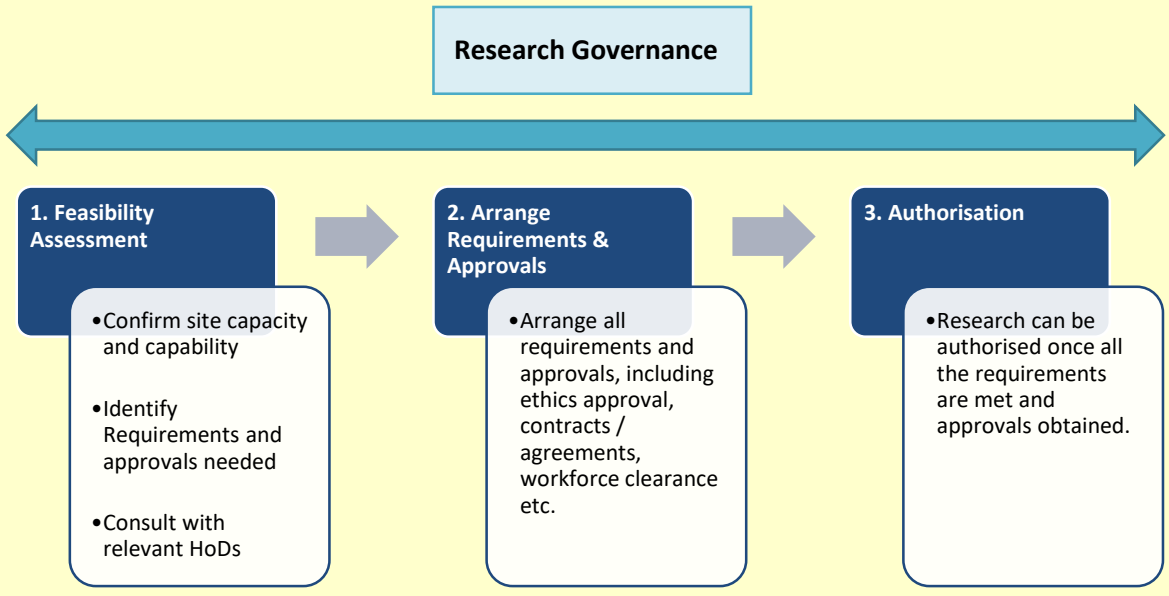
staff revealed that researchers often do not realise the extent of research governance requirements until after the submission of their SSA application. There are also researchers who are unaware of the existence of the SSA process, assuming that ethical approval is all they need to commence their research.

The NHMRC Research Governance Handbook (2011) suggests that it is best practice for each institution to "consider relevant local matters prior to or in parallel with ethical review" to avoid unnecessary delays in study start up. The RGO staff who were interviewed believed that the research governance process must commence as early as possible and preferably at the time of the research projects' feasibility assessment. They expressed concern that HRECs and RGOs spend significant amounts of time and effort to authorise research projects that do not eventuate due to poor feasibility assessments and / or lack of adequate consultation with relevant Heads of Departments (HoDs).

The researchers also highlighted this issue with one researcher stating in the survey that "instead of being vetted and not approving the insufficiently resourced studies, they are propped up and allowed to limp through to approval. As a result, I think there is a significant amount of research that is left unfinished and is a waste". This results in further stretching the resources of HRECs and RGOs and impacting their capacity for other research projects that are feasible and can result in positive outcomes.

Recommended Potential Solution/s

2. Through the interviews, RGO staff proposed establishing a more dynamic authorisation process starting at feasibility assessment and finishing at authorisation to address this issue.



If supported by all relevant stakeholders, this model could be operationalised through the methods outlined on the next page.

Toolkit & Checklist	REGIS	Role of RGO Staff
• Development of a toolkit for researchers providing guidance on research governance requirements and considerations (including feasibility assessments). • Development of an agreed, standardised and endorsed (mandatory) SSA submission checklist covering all research governance related requirements.	• Making the toolkit and checklist publicly available on the REGIS website and other relevant websites (e.g. local RGO websites) • Advising researchers at Project Registration on REGIS that they must use the toolkit to prepare their SSA applications and complete the mandatory checklist prior to submission.	• This model would require a change in culture and re-imagination of the role of RGO staff from gatekeepers to facilitators / coordinators. • RGO staff would provide support and guidance to researchers as they complete the checklist with the understanding that appropriately completed checklists result in SSA applications ready for authorisation.

NOTE: This model could be operationalised with any other ICT system such as a National One-Stop-Shop. The toolkit could still be made available and promoted for use and the checklist remain a mandatory requirement for all NSW PHO sites.

Over-Regulation

The literature review and survey with researchers revealed the research community's frustration with research governance review not being proportional to the level of risk in different research projects. Rush et al. (2017)[15] shared their experience of having spent 8 times as many researcher hours on regulatory compliance (60hrs) as on their study activities which included interviews with staff from 3 Biobanks to discuss facility operations (7.5hrs, 2.5hrs per site). White et al. (2016)[16] further suggest that "the NHMRC's recommendation that governance procedures recognise and reflect that different types of research pose different types of risk has not been adopted by most research offices."

RGO staff identified the 'one size fits all' approach of the existing policies and processes as one of the sources of this issue. They highlighted that existing policies and processes are mainly focused on clinical trials and lack guidance on conducting risk-based governance reviews for other types of research.

Additionally, 71.1 % of RGO staff who completed the survey indicated that they did not have a clear direction from their senior management as to what level of risk is acceptable for research to be authorised within their organisation. In the absence of clear directions and guidelines, RGO staff often feel the burden of responsibility to determine level of acceptable risk on their own and therefore become conservative and risk averse as a result.

Recommended Potential Solution/s

3. Identify best practice to inform revision and / or creation of policies and guidelines providing guidance and consistency on conducting risk-based research governance review (some RGOs recommended the inclusion of a risk matrix to guide review).

4. RGO staff also recommended creating a simplified SSA application form and a more streamlined review process for low and negligible risk research projects, similar to the existing access request arrangement.

   ***IMPORTANT NOTE**: The 'National One Stop Shop' platform will include a single national SSA form. It is, therefore, critical that feedback from this report is shared with the creators of the form and the new system.*

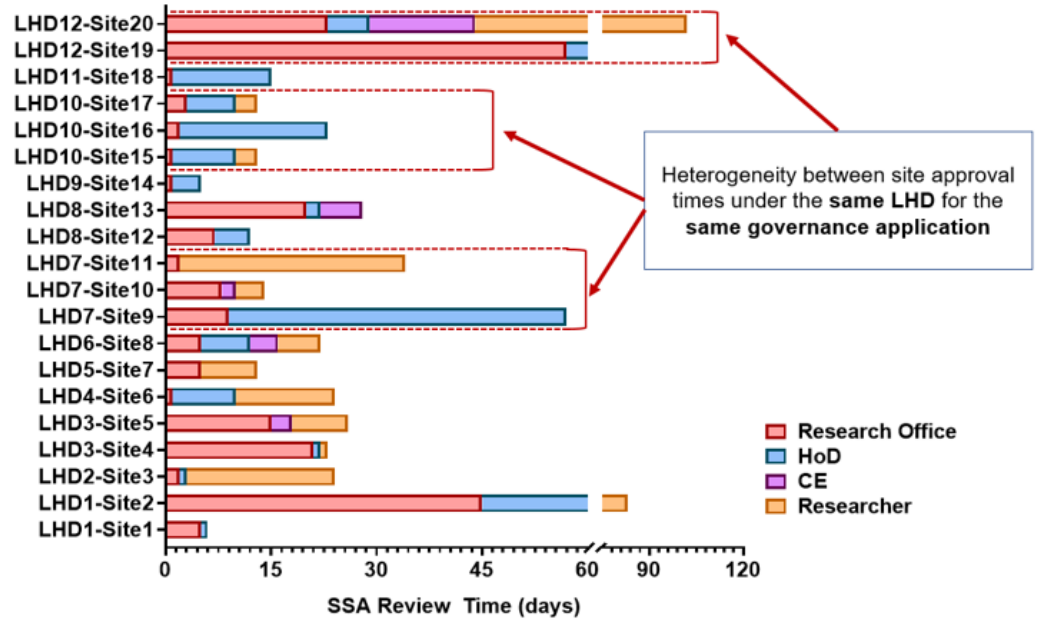
5. Consult with and seek input from senior management of PHOs on how their involvement could be strengthened and supported in further engaging with research governance processes.

Inconsistencies and Duplications

Inconsistencies and duplications in research governance requirements and processes were identified as major frustrations and issues by researchers and RGO staff. These issues have made the system unpredictable and difficult for researchers and sponsors to navigate. Data from REGIS further demonstrates variability in review timelines not only between different RGOs but also within the same RGO when reviewing the same research at multiple sites within their jurisdiction.

For example, the following graph demonstrates the variability in SSA review timelines for the same clinical trial conducted across multiple sites in NSW. A site is defined as "a facility, location or service where the research is being conducted". [29]

Graph 1.

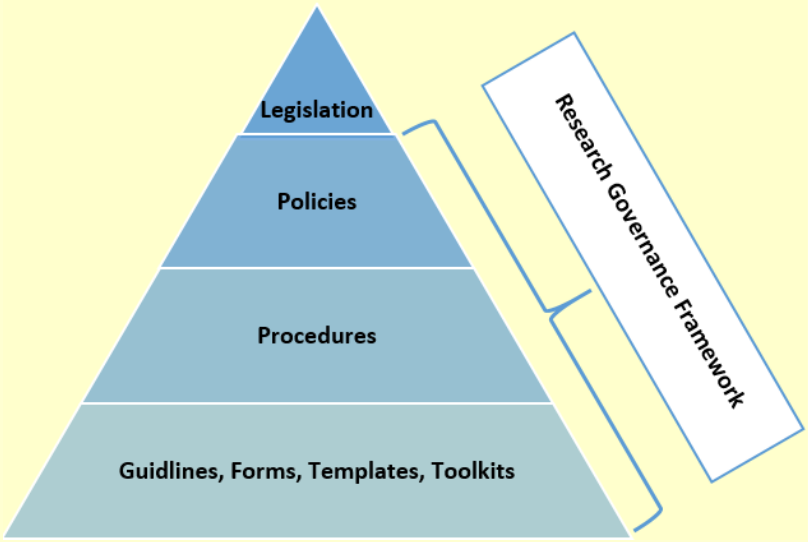


The main inconsistencies and duplications are examined in the subsequent sections of this report. At a high level, however, RGO staff identified gaps in state-wide policies and guidelines as one of the main drivers of these issues. Research governance policies and guidelines were considered to be out

of date and limited in their applicability and relevance to current practice. They were also considered to be open to interpretation allowing variation in practice.

Recommended Potential Solution/s

6. RGO staff strongly recommended standardisation of research governance processes and requirements at a state level. This could be achieved through the creation of a state-wide research governance framework translated into practice through concise high-level policies and detailed procedures, guidelines, forms, templates and toolkits to ensure consistent and standardised application of best practice across NSW PHOs.



Duplication between Ethical and Governance Reviews

Researchers voiced their concerns regarding the duplication between ethical and governance reviews. They identified the main areas of duplication as per the following:

- RGOs re-examining the ethical and scientific merit of research projects
- RGOs re-examining the ethical acceptability of Participant Information Sheets
- Researchers being required to replicate information about their study from the HREA (the ethics application form) to the SSA form. RGO staff also commented that the SSA form is designed to provide overall study information rather than site specific details required for an efficient RGO review.

In response to the RGO survey, 30.6 % of the respondents indicated that they had concerns with accepting ethical review from external HRECs under the NMA scheme. This group of RGOs were concerned regarding variations in standards of review by the different HRECs and their different approaches to risk management. Furthermore, the NHMRC Research Governance Handbook (2011) acknowledges that “there may be times when ethical consideration of a project by an HREC will draw on matters of relevance to the institution’s research governance responsibilities and vice versa” and that “a project that an HREC has deemed ethically appropriate may be inconsistent with one or more institutional policies.”

It is, therefore, essential that in addition to formulating solutions to minimise duplication between ethical and governance review, guidelines are also provided to RGOs on how to efficiently address governance issues that impact the ethical acceptability of research at their sites.

Recommended Potential Solution/s

7. Revise the SSA form to minimise duplication of information between the HREA and SSA. Inclusion of questions similar to the HREA will inevitably prompt the RGO reviewer to re-examine the same information previously reviewed by the HREC. RGO staff recommended revising the SSA form so that it is mainly focused on site-based activities and requirements.

8. Provide education and support to RGO staff to promote enhanced understanding of the scope of RGO reviews. The education packages and guidance must acknowledge that there are times when site specific governance matters impact the ethical acceptability of research at a particular site. RGO staff would welcome and require guidance on best practice in efficiently managing such situations.

9. Enable early commencement of research governance considerations so that any site-specific issues can be identified and addressed prior to or in parallel with the ethical review.

Multiple SSAs for Sites within the Same Jurisdiction

Researchers queried as to why some PHOs do not allow the submission of one (1) SSA application form for multiple sites within their jurisdiction. They felt that they were replicating the same information on multiple forms for the same RGO to review. Foot et al. [17] raised concerns that approvals of the same SSA for three hospitals in one PHO each took 44 days, with 27 emails for clarifications. Buck et al. (2020)[18] also found that "there was extensive duplication across applications; even where there were multiple hospitals within the same health district, separate full applications were still required for each site, despite being reviewed by the same governance officer and authorised by the same executive".

Only 18.9 % of the respondents to the RGO survey indicated that they do not accept a single SSA application for multiple sites within their jurisdiction. The reasons provided by this group included different research governance arrangements at each site and the inability to capture site specific information for each site on the current SSA form.

Recommended Potential Solution/s

10. Revise the SSA form to provide separate sections for multiple sites within the same jurisdiction so that site-specific information for each site can be provided within a single form.

11. Revise policies and guidelines to ensure consistency in accepting a single SSA form for multiple sites within the same jurisdiction.

Screening & Clearance of Researchers

RGO staff had different understandings and / or opinions regarding the role of RGOs in screening and clearance of researchers. Whilst a small group considered it their responsibility to assess researchers' qualifications and experience, many believed that the HoDs or Coordinating Principal

Investigators (CPIs) / Principal Investigators (PIs) should conduct this assessment and RGO staff should confirm the researchers' employment status and affiliations, insurance and GCP compliance (if applicable). There were also those who thought that RGOs should not partake in screening and clearance of researchers and that it should be managed by the HoDs, CPIs / PIs and the Workforce department of the PHOs.

Both RGO staff and researchers highlighted the variability in requirements and processes in screening and clearance of researchers between different PHOs. Researchers also complained regarding duplicate screening checks for the same researcher requiring access to multiple PHOs and the excessive level of documentation required in some instances.

Researchers further noted that the requirement for site PIs to be an employee of the site is not always practical, especially for multi-centre low and negligible risk projects that involve minimal site activities (e.g. online surveys / collection of electronic data). RGO staff responding to the survey were divided on this issue with 53.8 % of the respondents believing that the site PIs should be an employee of the site. Some responses revealed a misunderstanding that by not having a local PI, there will be no PI for the site at all and therefore no accountability from the research team. Some noted that an external PI would not be familiar with the organisational culture and processes while others were concerned regarding managing misconduct and complaints when a PI is external to the organisation.

Recommended Potential Solution/s

12. Identify best practice to inform revisions and / or creation of policies and guidelines providing guidance and consistency on the role and responsibilities of RGOs in screening and clearance of researchers.

13. Majority of the RGO staff who completed the survey (96.2 %) supported a state-wide research passport system to standardise procedures for contingent worker and honorary appointments for multi-centre research projects. A similar system has been established by the UK Health Research Authority (click on this link for more information). Additionally, AHRTCs in NSW are leading an initiative to introduce a similar model in NSW.

14. Identify best practice to inform revisions and / or creation of policies and guidelines providing guidance and consistency on when it is appropriate for an external researcher to act as PI for a site. It is also important that RGOs are empowered with adequate guidance and tools on how to manage and / or escalate research misconduct and complaints including those involving PIs external to their organisation (e.g. through creation of a research integrity policy / guideline / procedure).

Research Contracts / Agreements

Research contracts / agreements were considered to cause major delays in the research governance review processes. Apart from lengthy negotiations, RGO staff and researchers also identified inconsistencies and lack of clarity regarding when and what type of agreements / contracts are required for non-clinical trial research. RGO staff further indicated that they often do not have the capacity or expertise to review non-standard agreements / contracts. Only 7.4 % of the RGO respondents indicated that they had a legal background.

RGO staff also referred to limited access to legal support as a barrier to efficient management of research contracts / agreements. Only 27.3 % of the RGO respondents indicated that their organisation has a research legal officer. Therefore, RGO staff frequently seek or require legal support from either their organisational counsel / legal officers or external lawyers. Some RGO respondents expressed concern that organisational counsel / legal officers may not have an adequate understanding of the research landscape and not consider research a priority in their workload. Additionally, engaging external lawyers could be prohibitively expensive.

RGO staff further explained via the interviews that the process becomes even more complex by the initiation of the contract / agreements review at the time of the SSA submission which is too late in the process. This issue was also identified by the researchers with one researcher stating in the survey that "the person responsible for ensuring the contract is in order is the last person to review, often once partially executed causing delays in execution and additional work for the sponsor."

Recommended Potential Solution/s

15. Majority of the RGO respondents (96 %) supported state-wide standardisation of non-clinical trial contracts / agreements such as data / material transfer agreements and research collaboration agreements.

16. 76 % of the RGO respondents supported centralisation of legal review for non-standard agreements. Those who did not support centralised legal review were concerned that it would be challenging to manage legal review for multiple organisations in an efficient manner.

17. Identify best practice to inform revisions and / or creation of policies and guidelines providing guidance and consistency on when and what type of research agreements / contracts are required.

18. Explore and identify strategies to increase the availability of research legal support to RGO staff.

19. Enable early start of research governance considerations so that legal review of agreements / contracts can be initiated as soon as possible.

Head of Department (HoD) Approvals

Researchers identified the difficulty in obtaining timely approvals from the relevant HoDs as a barrier to efficient study start up. The main challenges were:

- Identifying who the right HoDs are.
- Details of the HoDs not being available / up to date on REGIS.
- Lack of appropriate delegation for HoDs on REGIS when they are on leave / busy.
- HoDs not having capacity to adequately utilise REGIS (REGIS emails getting lost in their inbox / forgetting REGIS password due to infrequent logging into the system).

- HoDs not having the capacity to read all study documents to understand the research requirements from their department in an efficient manner. Researchers felt that the REGIS email to HoDs is not informative as to what the HoDs are being asked to approve.
- Researchers also noted that some HoDs are not engaged with the research governance processes and do not consider research a priority. This was echoed by RGO staff with only 34.2 % of the RGO respondents indicating that the HoDs in their organisation are engaged with the research governance processes.

Recommended Potential Solution/s

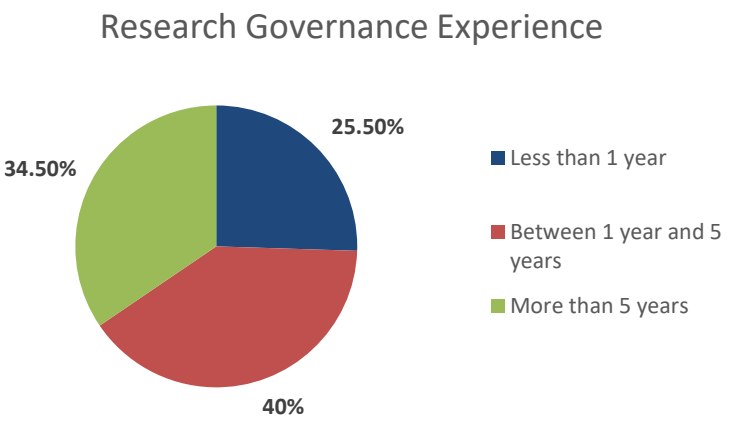
20. Consult with HoDs on how they could be supported to better engage with research governance processes and provide timely approvals.
21. Establishment of trial set-up meetings at PHOs that would include the relevant HoDs (or their representatives) to facilitate efficient consideration and recording of support / lack of support for a clinical trial. The Royal Marsden Hospital (UK) has successfully established this arrangement which could be used as a model for NSW PHOs. The Royal Marsden Hospital's trial set-up meeting "ensures that the right people – the investigator, pharmacy, radiology, finance and contracts – are gathered weekly to discuss new trials to be run in the hospital. This helps to quickly resolve issues that would usually delay the set-up of trials." [23]
22. For non-clinical trial research, create a tiered system as to when HoD approval is required to reduce burden on HoDs and enhance their capacity for efficient consideration of research that impacts their department. The UK's "HRA Approval: Assessment Criteria and Standards Document" includes a table (pg. 4-5) that provides examples of scenarios and considerations involved in determining when and what level of site approval may be required [24]. A similar model could be developed in NSW for HoD approvals.
23. Educate and enable researchers to engage HoDs as early as possible.
24. Facilitate provision of concise and clear information to HoDs regarding the impact of research projects on their department (e.g. revisions to the REGIS correspondence template).
25. Provision of education and guidance to HoDs on their role and responsibilities in authorising research.
26. Explore opportunities to improve REGIS processes for obtaining HoD approvals.

The RGO Workforce

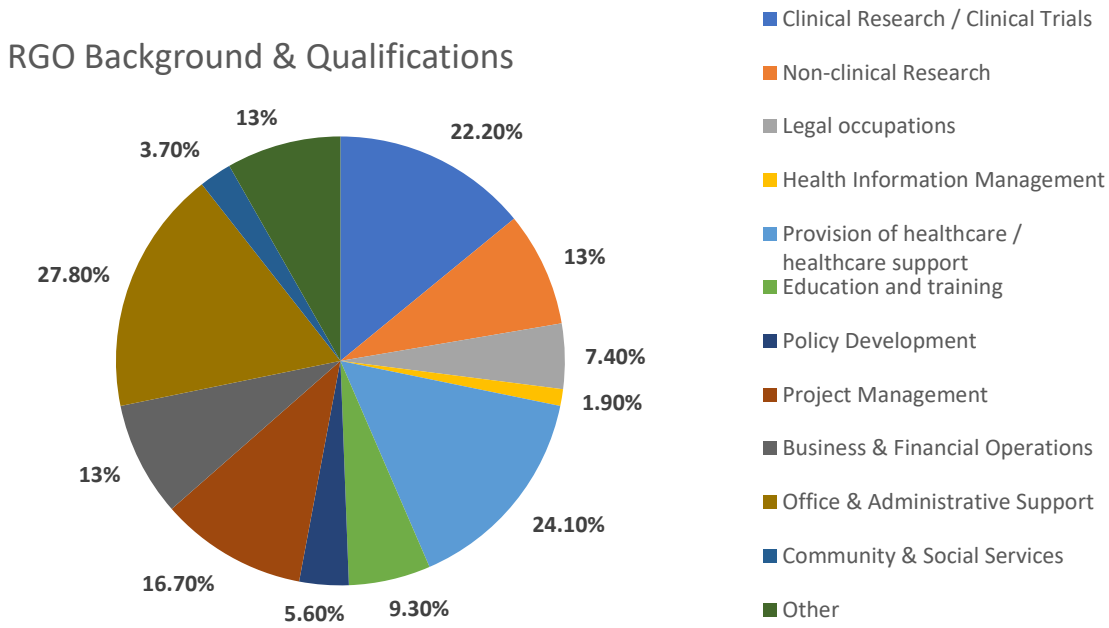
Workforce is the backbone and most tangible asset of any organisation. Despite its importance, the RGO workforce is often overlooked when analysing gaps and / or strengths of the research governance system. The implementation of technical and / or strategic solutions could only be successful if there was an equal and parallel investment in the workforce.

The RGO survey revealed that the NSW RGO workforce is comprised of staff with varying degrees of research governance experience and different qualifications and expertise.

Graph 2.



Graph 3.



Workforce diversity is a strength to be celebrated. Nonetheless, in the absence of central research governance training, each employee will understand and therefore implement research governance through the lens of their individual experiences and qualifications. When RGO staff were asked regarding how they learnt about research governance when they first started working in the sector, 100 % of the respondents indicated that they learnt on the job. One of the respondents stated “most RGO [staff] are trained like junior Drs - see one, do one, teach one.” Only 26.9 % of the respondents were very confident in their understanding of the current research regulatory requirements while 46.2 % were moderately confident. The interviews further revealed that it is challenging for the less experienced RGO staff to navigate the research governance regulatory landscape in the absence of adequate training, clear policies and a support network.

Additionally, 84 % of the RGO respondents described their office as under-staffed, and 60 % did not find the RGO workload reasonable. The RGO staff participating in the interview described the current workforce as lacking stability and resilience to the point that any staff departure or temporary staffing issues significantly impact service delivery. Barnett et al. (2016)[19] found that

frequent staffing changes resulted in variability in the speed with which the RGO staff responded to both general enquiries and reviewing applications.

RGO staff were supportive of the strategic drive for more research and its integration into clinical care. They were, however, concerned regarding the lack of sufficient investment in the RGO workforce to adequately cater for the increasing demand for their services. An understaffed, unconfident and unsupported workforce simply cannot have the capacity for high performance whilst also managing an increasing workload. Moreover, being understaffed with a heavy workload results in RGO staff focusing on authorising new research without the capacity to adequately monitor existing research. This is a significant risk to the PHOs, especially if they also sponsor research. Good Clinical Practice (GCP) requires that sponsors monitor research at all stages through a "systematic, prioritised, risk-based approach"[20].

Recommended Potential Solution/s

27. Develop a central research governance training course for RGO staff (e.g. via HETI).

28. Update the document "Operations Manual: Research Governance Officers (GL2010_015)" based on best practice.

29. Provision of ongoing education and professional development opportunities for RGO staff. The RGO staff participating in the interviews called for strategic stewardship and leadership from NSW OHMR to guide and support the sector in learning about best practice and implementing it.

30. RGO staff also strongly recommended the appointment of an Education Officer / Manager at NSW OHMR who could coordinate all research ethics and governance educational activities and act as a point of contact for RGO staff requiring guidance and / or advice.

31. Consult with and seek input from senior management of PHOs on how they could be supported in analysing the gaps in their RGO workforce for a more informed workforce planning.

Researcher Education & Quality of Applications

Poor quality applications take a long time to reach authorisation. RGO staff are concerned that researchers do not understand research governance requirements and / or do not value the process. Many researchers also confuse research governance with research ethics as also demonstrated by the responses received to the researcher survey for this project. A number of the respondents had referred to research ethics processes and requirements when asked about their research governance experience.

Despite the clear need for researcher education, 69.2 % of the RGO staff who completed the survey indicated that they do not have the capacity and resources to educate researchers on research governance. The websites of different NSW PHOs offer different levels of information and guidance to their research community. Barnett et al. (2016)[19] refer to the "lack of clear, consistent or available guidelines for application requirements" as one of the major challenges faced by their team. Samir

et al. (2021)[21] found "few RGOs provided upfront, clear guidelines about the documents required for submission."

RGO staff further suggested that in addition to providing information and guidelines, researchers need practical support in preparing their applications. Commercially sponsored research projects were generally associated with better quality applications compared to investigator-initiated ones. Availability of support and resources to the research team were mentioned as the differentiating factors. Investigator-initiated research is often conducted by time-poor clinicians who prepare their research governance applications without adequate support and based on a limited understanding of the research regulatory landscape. A researcher stated in the survey that "we are not experts and we rely on the help of RGO to assist us and facilitate the process where they can through information, personal guidance and help preparing applications (rather than simply receiving feedback for change after the fact.)."

Additionally, RGO staff raised concerns during the interviews that the majority of the research community have the misconception that the SSA process equates to research governance. They were hoping for the outcome of this project to challenge this misconception and produce a framework that clearly defines research governance as encompassing a number of areas including both strategic and operational matters during the entire lifecycle of a project.

Recommended Potential Solution/s

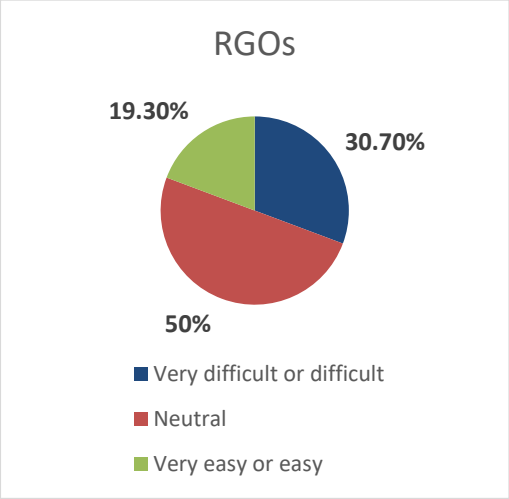
32. NSW OHMR to support PHOs in providing education and guidelines to researchers through the following methods:
    - A central research governance training course for researchers
    - Creation of a research governance toolkit and submission checklist as also mentioned earlier
    - Development of a central webpage (e.g. on the REGIS website) that provides information and guidance on research governance submission requirements and processes of NSW PHOs
33. Making the submission checklist and / or the SSA form educational so that researchers are educated about the processes and requirements as they complete the form.
34. Consultation with senior management of PHOs, AHRTCs and NSW Regional Health Partners regarding the feasibility of providing study start up and educational support to researchers within their organisation / partnerships.

REGIS

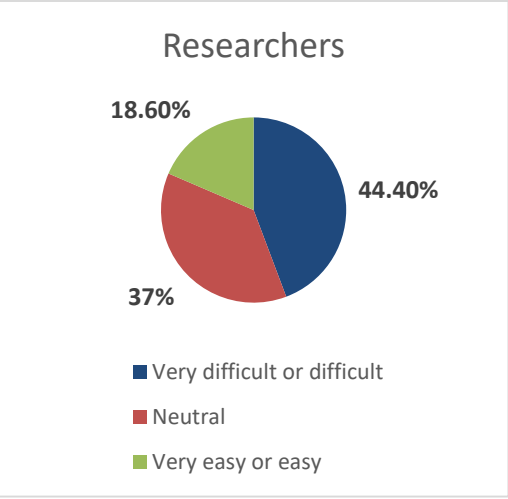
REGIS is the portal through which NSW PHOs manage research ethics and research governance applications. REGIS was introduced in 2018 to replace the previous platform which was operationalised through AU RED and Online Forms.

When RGO staff and researchers were asked as to how easy they find using REGIS, they responded as per the below diagrams:

Graph 4.



Graph 5.



The strengths of the system were identified as per the following:

- Automatic linkage between ethics and governance applications
- Automation of tasks such as generating recipients of correspondence, correspondence templates and automatic tracking of HREA changes.
- Being a single electronic repository and record of approvals and projects
- REGIS being able to facilitate standardisation of requirements once achieved at a high level

The following were identified as the most frustrating aspects of REGIS:

- Its complex and non-intuitive workflow. A researcher explained in the survey that "you need ongoing training to use it and have to rely on the helpdesk to trouble shoot. Basically you can't just log in and be guided through the process".
- Document management
- HoDs approval processes
- Frequent changes to the system
- System errors and the difficulty in identifying the sources of the errors. A researcher explained in the survey that "even if we follow the correct steps, there is a chance it doesn't work due to technical issues… and it takes quite a while to get to the point of realising it is definitely a technical issue and not due to doing the wrong thing."
- System slowness

Recommended Potential Solution/s

35. Sharing the survey results with the REGIS team at NSW OHMR to inform ongoing system quality improvement activities.

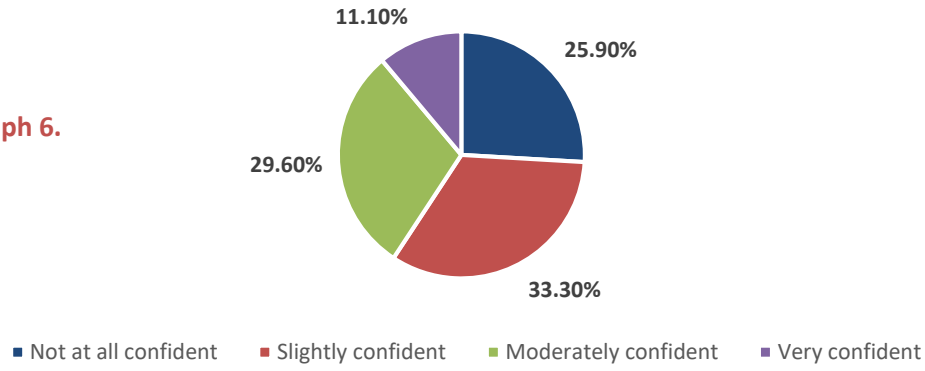
36. Utilising this feedback to inform the NSW response to consultations on the proposed national health and medical research approvals platform (National One-Stop-Shop).

National Clinical Trials Governance Framework

The Australian Commission on Safety and Quality in Health Care, on behalf of all jurisdictions, developed the National Clinical Trials Governance Framework (the Framework) following national consultation. The Framework is the first step towards the accreditation of health service organisations for the provision of clinical trial services and aims to embed clinical trial services into existing clinical and corporate governance systems. Implementation of the Framework is anticipated to commence in 2022 [22].

The RGO staff survey revealed their varying levels of confidence in relation to the Framework.

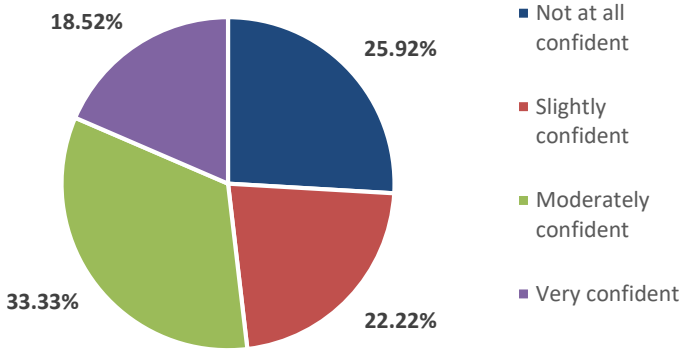
Graph 6.



RGO respondents were concerned regarding their limited capacity and resources to adequately learn and fulfil the requirements of the Framework in a timely manner. Implementation of the Framework will require collaboration between various stakeholders at an organisational level including the Executives, corporate and clinical governance, researchers and consumers. RGO respondents, however, indicated that there has been limited engagement from those stakeholders to date.

When RGO staff were asked how confident they are in their understanding of the interconnections between clinical governance, corporate governance and research governance, their responses showed a high degree of variability.

Graph 7.



The Australian Commission on Safety and Quality in Health Care defines corporate governance as the "establishment of systems and processes that shape, enable and oversee management of an organisation". It further explains that clinical governance is an integrated component of corporate governance to ensure "delivery of health services that are safe, effective, integrated, high quality and continuously improving" [25]. The Commission also provides the following diagram to illustrate the multiple components of corporate governance:

The NHMRC Research Governance Handbook (2011) places research governance at the centre of this diagram by highlighting that research governance "addresses protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management and monitoring arrangements and promotes good research culture and practice." It is, therefore, essential that NSW PHOs operate based on a strong and consistent research governance framework that is well-embedded within the overall corporate governance framework of their institution.

Recommended Potential Solution/s

37. Organisation and delivery of webinars / education sessions by NSW OHMR / HETI to PHOs summarising the Framework and its requirements. The sessions could also provide best practice guidance on how PHOs can satisfactorily meet the requirements of the Framework.

38. Consult with and seek input from senior management and RGO staff of PHOs on how research governance could be better embedded within the overall corporate and clinical governance of PHOs. Utilise information gathered from these consultations to inform revisions of policies and guidelines accordingly.

Performance Measurement

Performance measurement is key to the success of any organisation. As Peter Drucker said, "it is not possible to manage what you cannot control and you cannot control what you cannot measure". Key Performance Indicators (KPIs) assist organisations in monitoring performance and identifying areas

that need action and / or improvement. It is essential that KPIs are formulated systematically and based on evidence to achieve intended results.

RGO respondents raised concerns during the interviews that research ethics and governance KPIs are solely focused on review timelines of new research projects with no considerations of other factors such as quality of research, other RGO workload (e.g. review of amendment applications) and level of resources available to them. It was their view that a holistic and evidence-based approach to the development and implementation of KPIs is highly needed. The Balanced Scorecard Institute explains that good KPIs "can track efficiency, effectiveness, quality, timeliness, governance, compliance, behaviours, economics, project performance, personnel performance or resource utilisation" [26]. Such strong KPIs would be a strong tool for Executives, senior management and RGOs at PHOs in identifying and addressing issues impacting their research governance performance.

RGO respondents also recommended the introduction of a central ongoing customer satisfaction survey to engage researchers and ensure the tailoring of service delivery to their needs.

Recommended Potential Solution/s

39. Re-consider the current Research Ethics and Governance KPIs in consultation will all relevant stakeholders including service providers (i.e., RGO staff, Executives and senior management of PHOs) and service users (i.e., researchers and Industry). If change in KPIs is supported, it is strongly recommended that expert consultants are engaged to ensure reformulation of strong KPIs that could work as a guiding compass for decision makers. Successful achievement of this aim could result in other jurisdictions adopting the NSW KPIs and hence making NSW lead nationally in this area.

40. Development and delivery of a central ongoing customer satisfaction survey by NSW OHMR. Link to the satisfaction survey could be made available within the REGIS correspondence to researchers. Results could be collated and made available to PHOs on a regular basis (e.g., quarterly).

Change Management

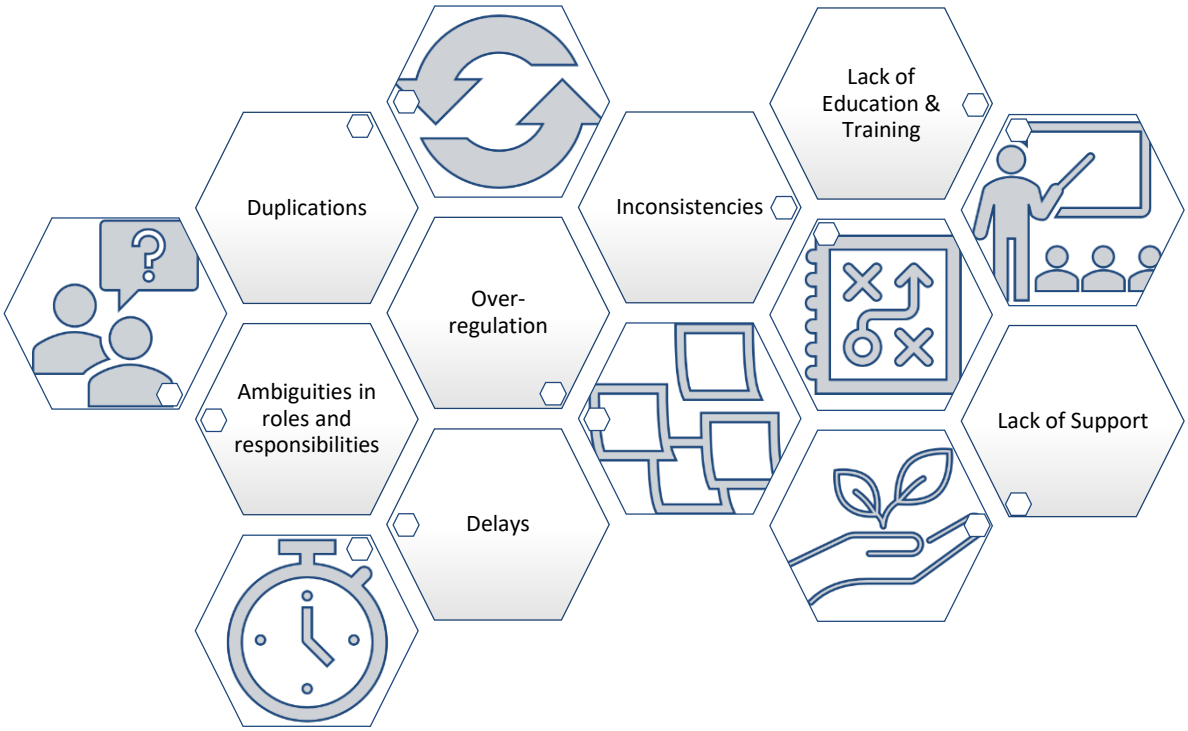
Designing change is a challenging exercise. It is even more challenging to communicate and implement change in an effective and efficient manner. Poor change management results in wastage of resources and efforts with limited or no benefit realisation in return. This negatively impacts on the morale of the change recipients and increase their resistance to change in the future.

Through the consultations, RGO staff and researchers expressed their fatigue with previous projects and initiatives not having achieved the intended results. Their experience could be best captured by the phrase coined by the French writer Jean-Baptiste Alphonse Karr, "the more things change, the more they stay the same". RGO staff further shared their apprehension that changes resulting from this project would be implemented without adequate consultation and with limited guidance and resources made available to them.

A structured, well-communicated, supported and inclusive approach to the design and implementation of change is, therefore, vital to the success of this project.

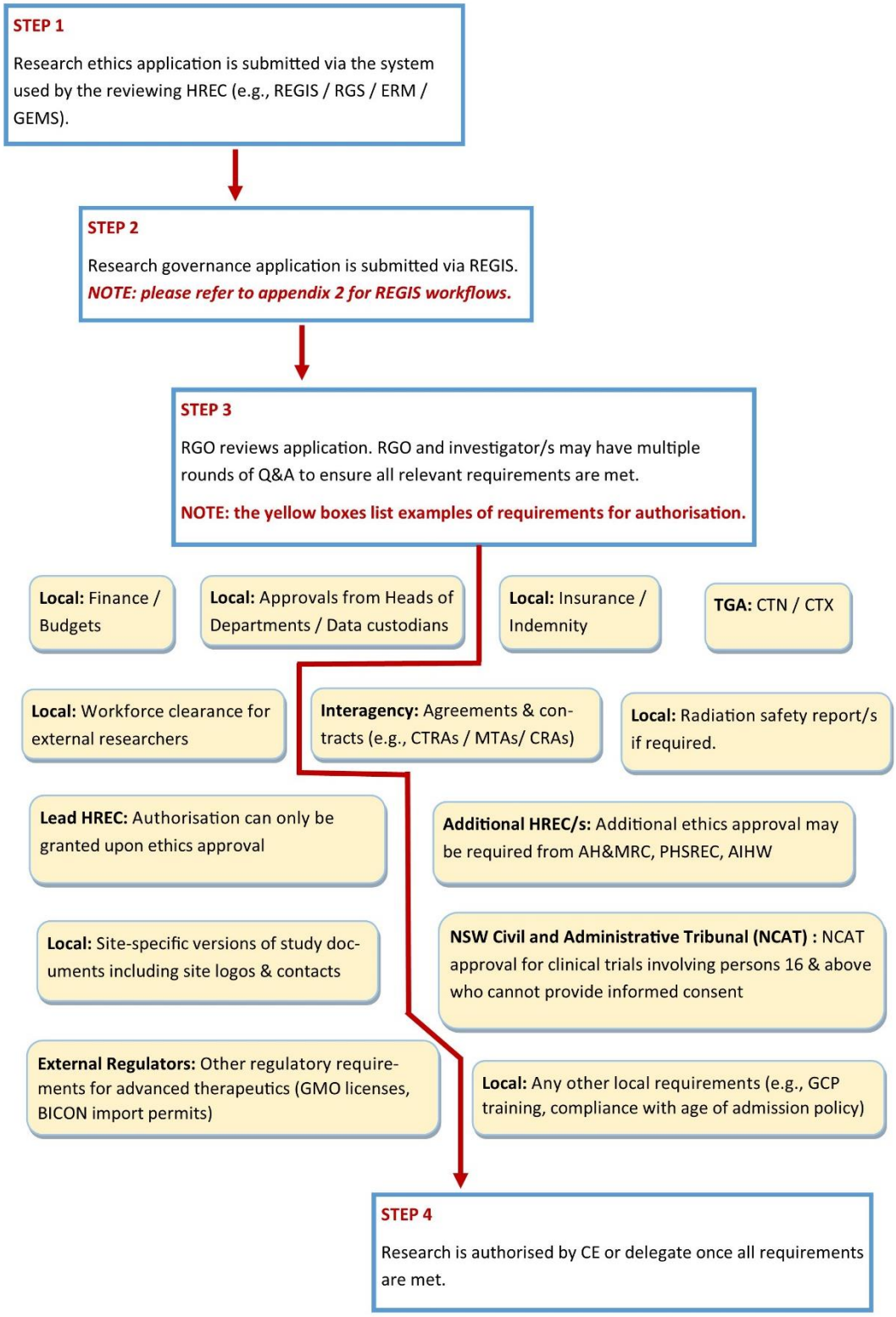
Conclusion

In conclusion, phase one (1) of the research governance project demonstrated that issues impacting research governance in NSW are multifaceted and occur at different stages of the process.

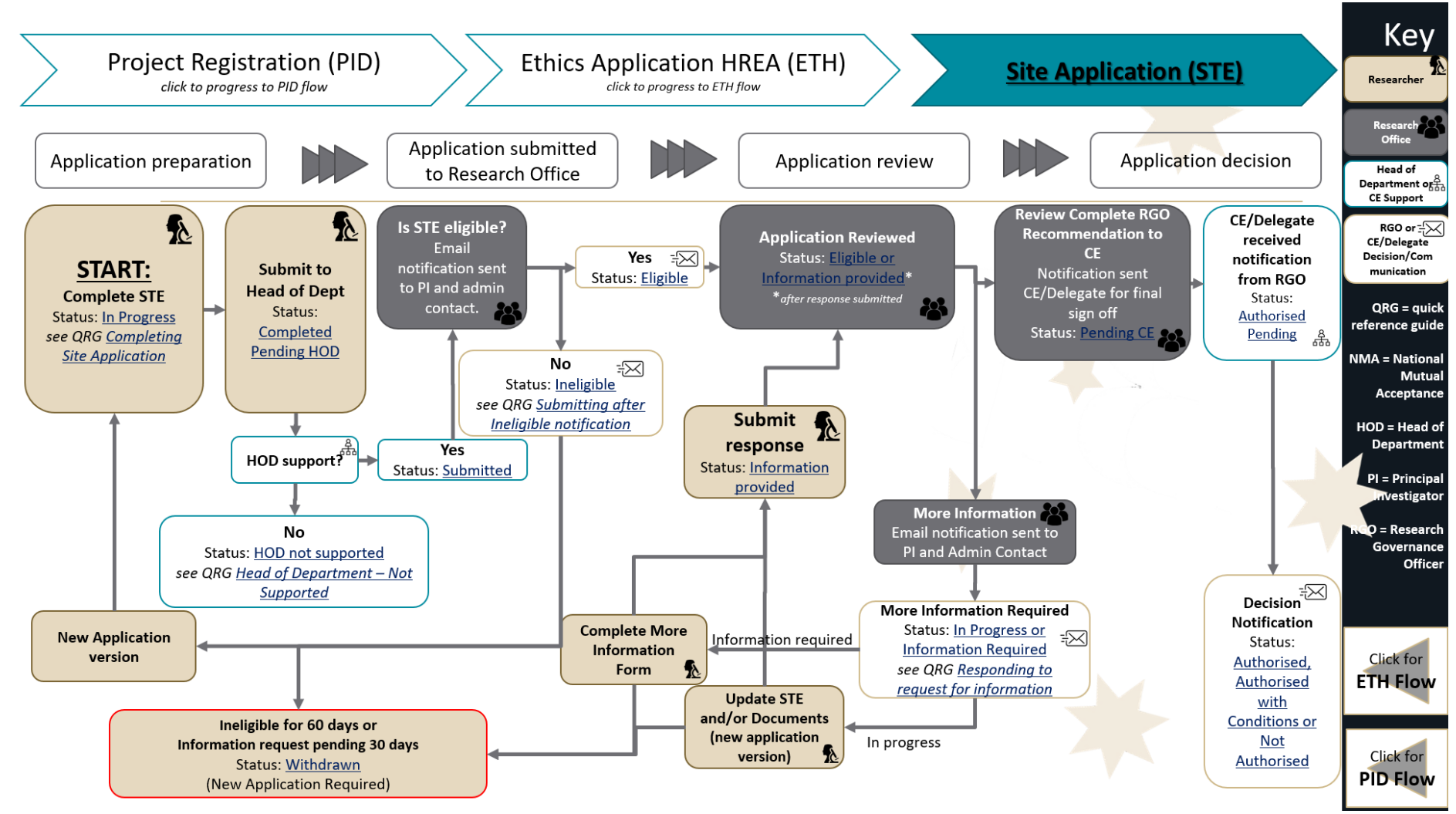


Phase two (2) of the project is due for completion by the end of April 2022. Proposed solutions will be formulated in consultation with all relevant stakeholders including RGO staff, PHO Executives, NSW OHMR, researchers and Industry partners. Each proposed solution will be accompanied by a description of resources and timelines required for implementation, evaluation and monitoring.

Appendix 1 – Current Research Governance Workflow



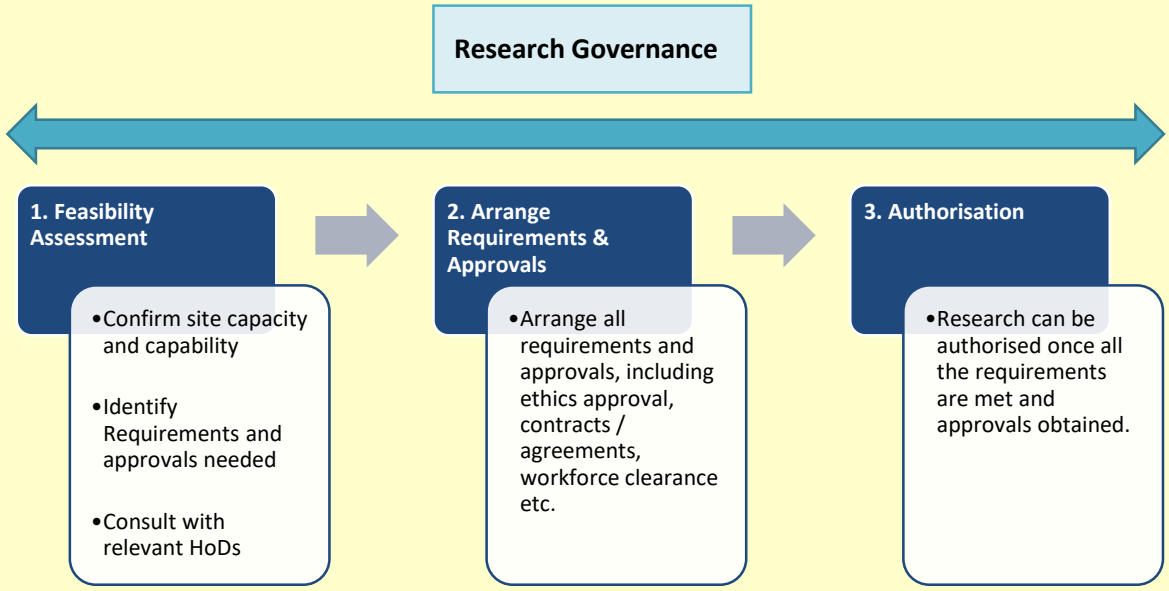
Appendix 2 – REGIS Authorisation Workflow



Appendix 3 – List of Recommended Potential Solutions

1. Learning from this experience, this project recommends further developing the concept of research governance and establishing a 'Research Governance Framework' for NSW PHOs which clearly defines the roles and responsibilities of all relevant stakeholders including the institutions (hosting and / or sponsoring research), researchers and external sponsors. It is essential that the framework is dynamic and responsive to a rapidly changing research environment including other initiatives such as the National Clinical Trials Governance Framework and the potential establishment of a national health and medical research approvals platform (National One-Stop-Shop). Strategies must be put in place to continuously evaluate and improve the framework to ensure its clarity, adequacy and relevance over time.

2. Through the interviews, RGO staff proposed establishing a more dynamic authorisation process starting at feasibility assessment and finishing at authorisation to address this issue.



If supported by all relevant stakeholders, this model could be operationalised through the methods outlined on the next page.

Toolkit & Checklist	REGIS	Role of RGO Staff
• Development of a toolkit for researchers providing guidance on research governance requirements and considerations (including feasibility assessments). • Development of an agreed, standardised and endorsed (mandatory) SSA submission checklist covering all research governance related requirements.	• Making the toolkit and checklist publicly available on the REGIS website and other relevant websites (e.g. local RGO websites) • Advising researchers at Project Registration on REGIS that they must use the toolkit to prepare their SSA applications and complete the mandatory checklist prior to submission.	• This model would require a change in culture and re-imagination of the role of RGO staff from gatekeepers to facilitators / coordinators. • RGO staff would provide support and guidance to researchers as they complete the checklist with the understanding that appropriately completed checklists result in SSA applications ready for authorisation.

NOTE: This model could be operationalised with any other ICT system such as a National One-Stop-Shop. The toolkit could still be made available and promoted for use and the checklist remain a mandatory requirement for all NSW PHO sites.

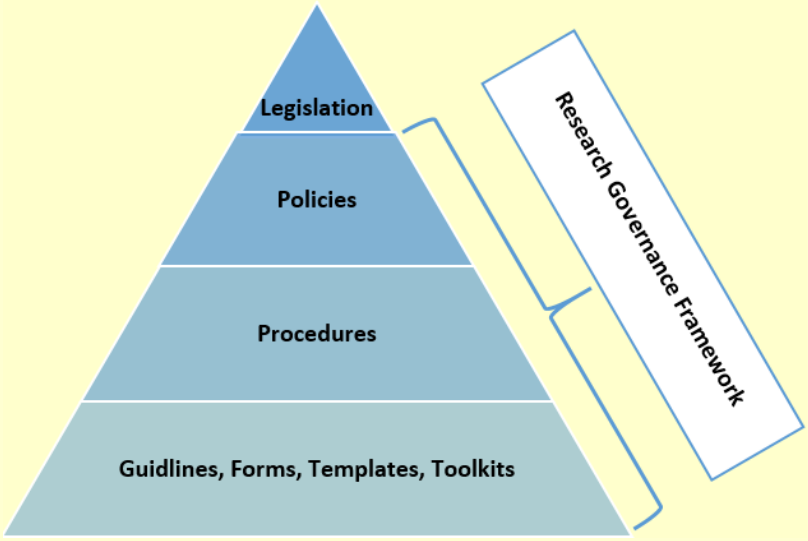
3. Identify best practice to inform revision and / or creation of policies and guidelines providing guidance and consistency on conducting risk-based research governance review (some RGOs recommended the inclusion of a risk matrix to guide review).

4. RGO staff also recommended creating a simplified SSA application form and a more streamlined review process for low and negligible risk research projects, similar to the existing access request arrangement.

   ***IMPORTANT NOTE**: The 'National One Stop Shop' platform will include a single national SSA form. It is, therefore, critical that feedback from this report is shared with the creators of the form and the new system.*

5. Consult with and seek input from senior management of PHOs on how their involvement could be strengthened and supported in further engaging with research governance processes.

6. RGO staff strongly recommended standardisation of research governance processes and requirements at a state level. This could be achieved through the creation of a state-wide research governance framework translated into practice through concise high-level policies and detailed procedures, guidelines, forms, templates and toolkits to ensure consistent and standardised application of best practice across NSW PHOs.



7. Revise the SSA form to minimise duplication of information between the HREA and SSA. Inclusion of questions similar to the HREA will inevitably prompt the RGO reviewer to re-examine the same information previously reviewed by the HREC. RGO staff recommended revising the SSA form so that it is mainly focused on site-based activities and requirements.

8. Provide education and support to RGO staff to promote enhanced understanding of the scope of RGO reviews. The education packages and guidance must acknowledge that there are times when site specific governance matters impact the ethical acceptability of research at a particular site. RGO staff would welcome and require guidance on best practice in efficiently managing such situations.

9. Enable early commencement of research governance considerations so that any site-specific issues can be identified and addressed prior to or in parallel with the ethical review.

10. Revise the SSA form to provide separate sections for multiple sites within the same jurisdiction so that site-specific information for each site can be provided within a single form.

11. Revise policies and guidelines to ensure consistency in accepting a single SSA form for multiple sites within the same jurisdiction.

12. Identify best practice to inform revisions and / or creation of policies and guidelines providing guidance and consistency on the role and responsibilities of RGOs in screening and clearance of researchers.

13. Majority of the RGO staff who completed the survey (96.2 %) supported a state-wide research passport system to standardise procedures for contingent worker and honorary appointments for multi-centre research projects. A similar system has been established by the UK Health Research Authority (click on this link for more information). Additionally, AHRTCs in NSW are leading an initiative to introduce a similar model in NSW.

14. Identify best practice to inform revisions and / or creation of policies and guidelines providing guidance and consistency on when it is appropriate for an external researcher to act as PI for a site. It is also important that RGOs are empowered with adequate guidance and tools on how to manage and / or escalate research misconduct and complaints including those involving PIs external to their organisation (e.g. through creation of a research integrity policy / guideline / procedure).

15. Majority of the RGO respondents (96 %) supported state-wide standardisation of non-clinical trial contracts / agreements such as data / material transfer agreements and research collaboration agreements.

16. 76 % of the RGO respondents supported centralisation of legal review for non-standard agreements. Those who did not support centralised legal review were concerned that it would be challenging to manage legal review for multiple organisations in an efficient manner.

17. Identify best practice to inform revisions and / or creation of policies and guidelines providing guidance and consistency on when and what type of research agreements / contracts are required.

18. Explore and identify strategies to increase the availability of research legal support to RGO staff.

19. Enable early start of research governance considerations so that legal review of agreements / contracts can be initiated as soon as possible.

20. Consult with HoDs on how they could be supported to better engage with research governance processes and provide timely approvals.

21. Establishment of trial set-up meetings at PHOs that would include the relevant HoDs (or their representatives) to facilitate efficient consideration and recording of support / lack of support for a clinical trial. The Royal Marsden Hospital (UK) has successfully established this arrangement which could be used as a model for NSW PHOs. The Royal Marsden Hospital's trial set-up meeting "ensures that the right people – the investigator, pharmacy, radiology, finance and contracts – are gathered weekly to discuss new trials to be run in the hospital. This helps to quickly resolve issues that would usually delay the set-up of trials." [23]

22. For non-clinical trial research, create a tiered system as to when HoD approval is required to reduce burden on HoDs and enhance their capacity for efficient consideration of research that impacts their department. The UK's "HRA Approval: Assessment Criteria and Standards

Document" includes a table (pg. 4-5) that provides examples of scenarios and considerations involved in determining when and what level of site approval may be required [24]. A similar model could be developed in NSW for HoD approvals.

23. Educate and enable researchers to engage HoDs as early as possible.
24. Facilitate provision of concise and clear information to HoDs regarding the impact of research projects on their department (e.g. revisions to the REGIS correspondence template).
25. Provision of education and guidance to HoDs on their role and responsibilities in authorising research.
26. Explore opportunities to improve REGIS processes for obtaining HoD approvals.

27. Develop a central research governance training course for RGO staff (e.g. via HETI).
28. Update the document "Operations Manual: Research Governance Officers (GL2010_015)" based on best practice.
29. Provision of ongoing education and professional development opportunities for RGO staff. The RGO staff participating in the interviews called for strategic stewardship and leadership from NSW OHMR to guide and support the sector in learning about best practice and implementing it.
30. RGO staff also strongly recommended the appointment of an Education Officer / Manager at NSW OHMR who could coordinate all research ethics and governance educational activities and act as a point of contact for RGO staff requiring guidance and / or advice.
31. Consult with and seek input from senior management of PHOs on how they could be supported in analysing the gaps in their RGO workforce for a more informed workforce planning.

32. NSW OHMR to support PHOs in providing education and guidelines to researchers through the following methods:
    - A central research governance training course for researchers
    - Creation of a research governance toolkit and submission checklist as also mentioned earlier
    - Development of a central webpage (e.g. on the REGIS website) that provides information and guidance on research governance submission requirements and processes of NSW PHOs
33. Making the submission checklist and / or the SSA form educational so that researchers are educated about the processes and requirements as they complete the form.
34. Consultation with senior management of PHOs, AHRTCs and NSW Regional Health Partners regarding the feasibility of providing study start up and educational support to researchers within their organisation / partnerships.

35. Sharing the survey results with the REGIS team at NSW OHMR to inform ongoing system quality improvement activities.

36. Utilising this feedback to inform the NSW response to consultations on the proposed national health and medical research approvals platform (National One-Stop-Shop).

37. Organisation and delivery of webinars / education sessions by NSW OHMR / HETI to PHOs summarising the Framework and its requirements. The sessions could also provide best practice guidance on how PHOs can satisfactorily meet the requirements of the Framework.

38. Consult with and seek input from senior management and RGO staff of PHOs on how research governance could be better embedded within the overall corporate and clinical governance of PHOs. Utilise information gathered from these consultations to inform revisions of policies and guidelines accordingly.

39. Re-consider the current Research Ethics and Governance KPIs in consultation will all relevant stakeholders including service providers (i.e., RGO staff, Executives and senior management of PHOs) and service users (i.e., researchers and Industry). If change in KPIs is supported, it is strongly recommended that expert consultants are engaged to ensure reformulation of strong KPIs that could work as a guiding compass for decision makers. Successful achievement of this aim could result in other jurisdictions adopting the NSW KPIs and hence making NSW lead nationally in this area.

40. Development and delivery of a central ongoing customer satisfaction survey by NSW OHMR. Link to the satisfaction survey could be made available within the REGIS correspondence to researchers. Results could be collated and made available to PHOs on a regular basis (e.g., quarterly).

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