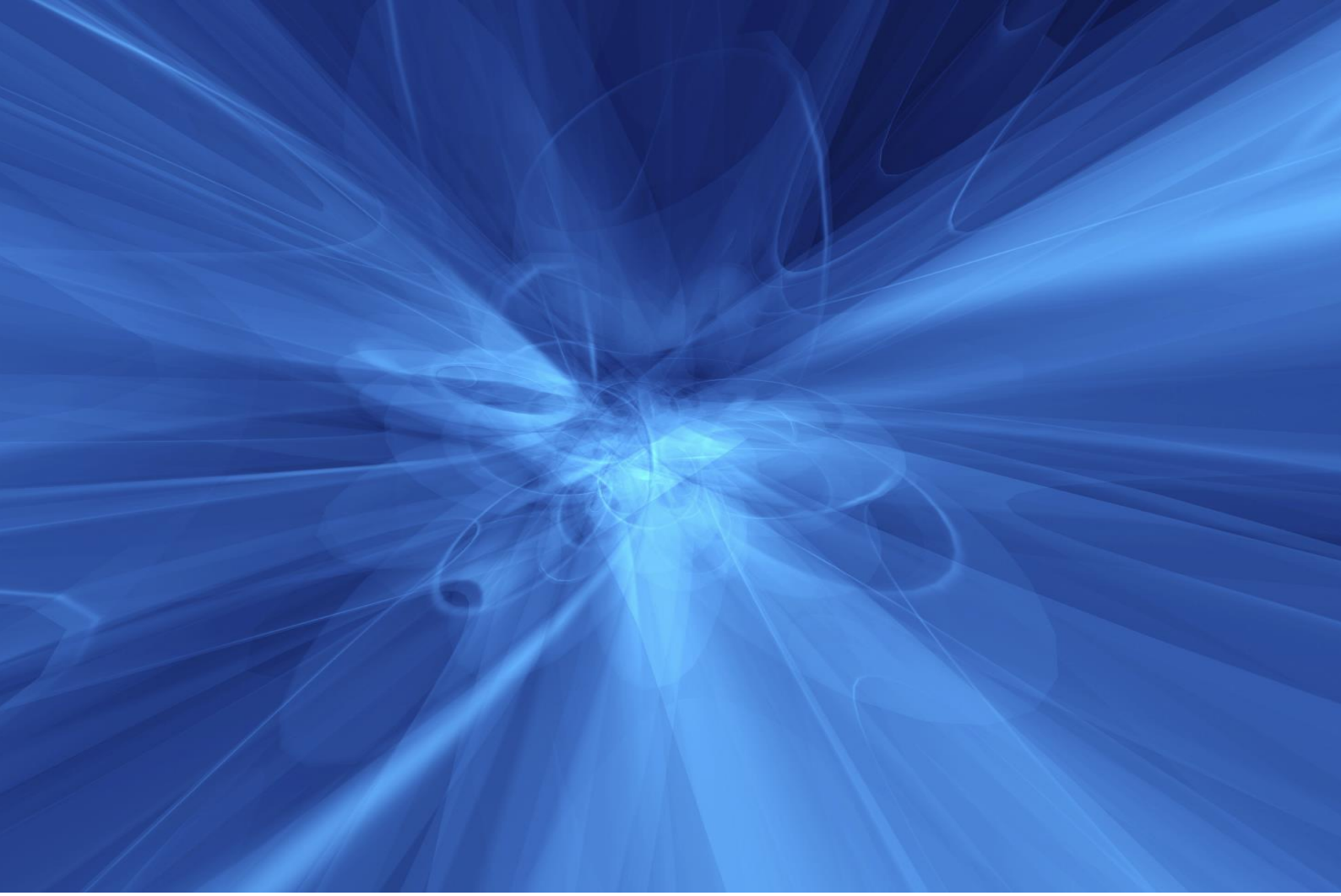

Review of Research Governance in the Department for Health and Wellbeing (SA) and related LHNs

Jim Birch Management Consultancy Pty Ltd

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The information in this report is based on interviews and documentation received in good faith from the various organisations and personnel who assisted with this engagement.

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1 Brief and methodology

The Department for Health and Wellbeing (SA Health) and its related agencies has had a formal approach to research governance in place since 2012, embedded within the Research Governance Policy Directive.(1) The current approach to research governance across SA Health separates human research ethics (HREC) approval from a formalised research governance review (site specific assessment, otherwise known as an SSA), with ongoing review and monitoring of approved research occurring through the supporting SA Health institution (LHN). This ensures projects are conducted appropriately and in accordance with applicable policies, guidelines and requirements.

The SA Health Office for Research is located within the Office for Professional Leadership, under Professor Paddy Phillips. The Office for Research was established as a state-wide service to provide coordination for health and medical research strategy and policy across SA Health. It also manages research ethics and governance for the Department for Health and Wellbeing.

Up until March 2018, there have been five Local Health Networks (LHNs) in South Australia. These include one in the South (Southern Adelaide Local Network - SALHN), one in the North (Northern Adelaide Local Network - NALHN), one in the Country (Country Health South Australia Local Health Network - CHSALHN), Women's and Children Hospital Network - WCHN and a Central Adelaide Local Health Network - CALHN. Central Adelaide research office, covers the Royal Adelaide Hospital (RAH), The Queen Elizabeth Hospital (TQEH), and also includes the Northern Adelaide Local Health Network ethics review and approval workload, covering Modbury Hospital and Lyell McEwin Hospital. The Central Office for Research reviews ethics applications for the Department for Health and Wellbeing and some other government agencies, but does not review clinical trials and does not charge any fees. Accordingly, there are four public sector Human Research Ethics Committees that review health and medical research projects being undertaken across the South Australian public health system.

There has not been an independent evaluation of the South Australian research governance approach since it was implemented and concerns have been raised by researchers about the efficiency of research governance review processes and the

perceived duplicative and bureaucratic nature of site specific assessments.

Internal discussions with Local Health Networks (LHNs) have raised concerns about the arrangements with the universities, in particular regarding research funding, contractual arrangements with external parties and requests for non-SA Health researchers to have access to patient records and confidential data.

Mr Jim Birch was engaged as an experienced independent consultant to undertake a research governance review encompassing all of SA Health examining current approaches and future requirements for research governance and more specifically ethics and SSA approvals. The review commenced in March 2018.

The governance review was required to include the following:

- The appropriateness of existing arrangements including resourcing, outcomes and consistency across the LHNs, State-wide Services and the Department for Health and Wellbeing.
- The relationship between SA Health and the South Australian Universities, the South Australian Health and Medical Research Institute (SAHMRI) and other external parties, with respect to the conduct of health and medical research.
- Whether approaches to monitoring and oversight of research are satisfactory and sufficient to identify instances of research misconduct, if and when these should occur.
- Any other related matters of significance.

The methodological approach to the review included targeted interviews with research governance officers at LHNs and in the Department for Health and Wellbeing, some researchers, senior Executive staff and some Chief Executives at LHNs and at the SA Health and Medical Research Institute (SAHMRI), University staff and relevant Faculty Heads as well as a senior Executive at Bellberry Ltd. For comparative purposes the research governance structure and processes in Victoria was considered and in particular at Monash Health. Additional interviews were also held with people experienced in intellectual property and commercialisation. A full list of interviewees is included in appendix 1.

In addition, the consultant conducted a targeted literature review, including a review of existing SA Health policies and relevant other documents. The consultant also applied his own knowledge and experiences to the analysis in order to determine conclusions and associated recommendations.

2 Executive summary and recommendations

It is important to provide a context and summary of observations and assessment of the current state in regard to research governance and support for research in the SA public health system and its related LHNs and concurrently to determine a possible future state. The lens in which the consultant viewed this was through a personal understanding of the outstanding history of research in years past and also a qualitative assessment of how South Australia compares at a jurisdictional level in regard to support for research activities. In addition, the consultant conducted a significant number of interviews and a targeted literature search to inform analysis and recommendations.

At the level of research governance, the consultant observed highly dedicated people working in difficult circumstances trying to provide robust governance oversight on behalf of the Department of Health and Wellbeing and LHNs, whilst at the same time supporting researchers and clinical trial applicants to achieve the best possible outcomes. In addition, it is clear that notwithstanding the relative inefficiency and variability of approach in research governance, applications for ethics approval are professionally considered by various committees and the consultant could not identify any obvious shortcomings in respect to ethical considerations. Nonetheless, it is clear that the processes leading to approvals can be improved considerably.

However, there is some evidence of a need for closer attention to audit and quality assurance of all processes in place, that should be assessed on a periodic basis. This includes study acquittal post ethics approval lapsing and ensuring appropriate close out of reports at the completion of research studies and clinical trials. Ensuring that this occurs is an appropriate role for the Department, however this may also entail inclusion in LHN internal audit programs.

In addition, it would appear that the current cost of providing research governance in public health services in South Australia is comparatively low when compared to a private sector comparator. A review of research governance costs in the SA public health system conducted in 2017 for the Department of Health and Ageing, estimated a cost of $3.5m per annum with a substantial component being funded from fees levied on grant applications and clinical trial applications. Cost of human ethics reviews for research was estimated at just under $2m per annum. The cost required to deliver the same service by Bellberry Pty Ltd (a not for profit provider), was compared and was estimated to be considerably higher than the public sector current cost. It is not appropriate to detail Bellberry's cost estimate in this report, as this is considered to be "commercial in confidence". In addition, it cannot be assumed from this that Bellberry is inefficient or "profit taking" in this regard. There are a number of possibilities that arise

from the comparison, including that the SA public health research governance functions are not well funded.

It is important to place on record that any commentary and recommendations made in this report are not a reflection on the individuals who work at the policy, coordination and research governance level within the health system. Without exception, I found all staff to be dedicated and receptive to change. Regrettably their efforts are directed specifically to the entities to which they are responsible, without a strong and consistent State-wide approach which could support process consistency, effective outcomes and results reporting and the application of an efficient and effective research governance process that would encourage more research within the SA Health system.

High levels of variation in practice and process were observed between organisations. This particularly pertained to the Human Research Ethics and SSA approvals process. This in part resulted from variable levels of resources being applied to these activities and a lack of cooperation between the LHNs and with the Department for Health and Wellbeing. It would appear that many of the processes pertaining to research governance are either developed according to perceived or real local needs, and frequently modified between each LHN. Resources were largely (but not wholly) generated from clinical trial application fees which were highly variable between LHNs resulting in substantial variation in research governance budgets even allowing for differences in LHN size. These fees are declining which in turn results in a high level of risk for research governance activities. The end result of this situation is a moderate to high level of frustration from researchers, who at times are subjected to unnecessarily variable approval processes and at times unacceptable delays for approval or decline of approval. This also is likely to lead (indeed it may already have) to a drift of clinical trial applicants to other sites in Australia where approval can be obtained more quickly. Importantly, it was difficult to find anyone who is satisfied with the current state of affairs, so for a variety of reasons there is a high degree of frustration.

As equally concerning, is the observable lack of support in most LHNs for research activities in general. It appears that research activity is now largely regarded as a discretionary cost and it is believed that where at all possible, infrastructure costs should be wholly covered through the respective research grants. Whilst this is logical for commercial clinical trials it is simply not practical for most non-commercial research grants. It is clear that over the past decade or so there has been a declining LHN corporate commitment to research. This seems to have in part arisen over several years from the obvious cost pressures incurred in providing services to patients, but is also likely to have been supported by a significant churn in Chief Executives at the LHN level, where KPIs relating to research activity and outcomes now appear largely non-existent to the assessment of LHN and CEO performance.

It is important to mention one LHN that appears to have developed consistent and highly robust approaches to research

governance and approvals processes. This is the Women's and Children's Hospital Local Health Network (WCHLHN). High levels of satisfaction were observed from researchers and importantly process time for approvals including SSA approvals matches best practice nationally. This is fortunate as it acts as a proxy in South Australia as to what is possible. To this end the consultant "unpacked factors which appeared to support high levels of performance at the WCH, in order to understand what may be needed elsewhere.

It is the consultant's view that there are too many HRECs in South Australia, given the size of the State's health system and the difficulty in attracting appropriate people to sit on Ethics Committees. There are a number of possible options going forward. For example, in time it may be possible to reduce the number of HRECs to three, with coverage based on the three main metropolitan geographies (north, south and central) with coverage also occurring in the three HRECs for WCHLHN and CHSLHN. Another option could well be to shift all research governance and ethics approval functions into the SA Academic Health Science and Translation Centre (SAAHSTC). However, at this stage the Centre's functions have not matured significantly, so such consideration of this option is premature.

Notwithstanding these options, the consultant remains unconvinced that centralisation (thereby creating a greater critical mass) will necessarily result in greater efficiencies and an improved service. It is noted that in Victoria a hybrid model exists which still provides for decentralised research governance at the LHN level along with localised ethics approval processes. This model also includes strong central coordination, support and oversight. If a similar model were to be implemented in SA as a first step, then it may not be necessary or desirable to move to a centralised model.

Accordingly, at this stage the consultant is not recommending a reduction in HRECs. In order to avoid destabilising the system in the short term, it is felt more important to achieve the following outcomes before considering further changes in the number of Ethics Committees and research governance secretariats;

- Use of high quality research governance practice software to be universally mandated across all of SA Health.

- Common application forms and processes to be applied across all of SA Health as a mandatory requirement.

- Funding of base levels of research governance support at LHN levels should not be reliant on clinical trial and research grant application fees.

- Support for research at the corporate level should be agreed and reflected in the development and application of KPIs in both the contracts for the Department for Health and

Wellbeing and LHN Chief Executive Officers

It is timely to review research governance in South Australia. It is not best practice, however it could be. Given the population size it should be comparatively easy to be the best and most efficient in Australia. There are incentives to achieve this. A report into the economic benefits of clinical trials in Australia has outlined the considerable benefits. However, it has also published a list of impediments, one of which is the high variability between sites regarding processes and the lengthy times to achieve ethics approval. (2)

Finally, it is timely to consider improvements to research governance given that a devolved Board governance system is being introduced to the SA public health system. This affords an opportunity to also examine the support required at the central Department for Health and Wellbeing level as well as at the LHNs. There is a process already underway to examine relative roles, functions and delegations of authority. Recommendations will also be made in this regard. It is noted that the paper published by SA Health titled "Research Focus 2020 Framework" (3) already includes an appropriate mission, goals and reportable KPIs. It is clear that execution of the contents of the Framework remains a key challenge and it is to this issue that the recommendations are largely directed as follows;

RECOMMENDATIONS

1.	Appropriate software be procured to ensure consistent management, database reporting and transparency of process for research governance activities. It is noted that this process is now underway and that every attempt should be made to procure software which is either identical to or compatible with procurements underway in Victoria, NSW and Queensland. Such software should also include the capacity to actively track grant and clinical trial application approvals and post approval management processes. These should be transparent to the principal grant and/or clinical trial applicant.
2.	Agreed average response times for SSA approval should be monitored. Where response times for applicants fall short of agreed KPIs by 20% then an applicant should be able to seek a Senior Executive review of the specific process that applies to their application.
3.	SSA approval should commence either before research ethics application assessment, or at the very least concurrently.

4.	A senior Executive at the LHN and/or Departmental level (depending on lodge location of application) should be the responsible officer for SSA approval and in ensuring a robust and efficient process. This should be at Deputy CEO level and the positon should be afforded an appropriate level of delegation of authority to minimise approval handover and process time.
5.	Research Governance Unit/Secretariats' should in the main be funded from the operating fund of the LHN or the Department (as the case may be) and not be dependent on clinical trial fees.
6	An audit of research infrastructure cost should be undertaken in order to determine whether the annual submission of research infrastructure cost to the Independent Hospital Pricing Authority is accurate. In addition, the audit should also examine whether the Commonwealth funding provided for research infrastructure through the National Health Funding Agreement is appropriately acquitted.
7.	As part of the devolution process between the Department for Health and Wellbeing and the LHNs, consideration be given to strengthening the central role within the Department for state-wide research leadership, strategy and policy development, audit and quality assurance and execution and oversight (not operations) of research governance standards and processes. A possible mechanism for funding the roles of both the central agency (the Department) and the LHNs is to top slice the allocation from the National Health Funding Agreement relating to research.
8.	The importance of health research to the State needs to also be reflected in the KPIs which apply to Chief Executive contracts of employment and the Services and Funding Agreements between the Department and the LHNs. Suggested KPIs are included in the report.
9.	Common forms and processes should be further developed mapped and applied (against best practice) and mandated for application to all organisations within the Department for Health and Wellbeing and the LHNs.

10.	State wide panels and/or appointment of expert subject matter individuals should be initiated. It is recommended that the Department for Health and Wellbeing Human Research Ethics Committee is best placed to provide ethical advice on data linking or if required to form a panel to expedite advice. Advice may also be required in areas such as gene technology and genomics in general along with a few other specialist areas where skill sets are hard to obtain.
11.	Develop common standards and criteria across all Ethics Committees in order to consistently assess low, medium and high-risk applications, in order to reduce the number of applications that are required to be referred to a formal Ethics Committee meeting.
12.	Develop standard approaches to clinical research at hospital level in regard to patient consent and engagement. This should include using electronic means of consent such as e-consent.
13.	Contract Bellberry Pty Ltd to undertake training in Ethics application assessment in order to achieve standard and consistent responses to applicants during the assessment process and also standard and consistent responses in regard to application risk rating.
14.	On the basis that Bellberry Ltd fulfil all NH and MRC requirements, SA Health and related LHNs should institute mutual acceptance for ethics approvals. This may not be suitable for multi-site approvals involving interstate sites in light of current National Mutual Acceptance policies.
15.	Further work be undertaken by Country Health SA to develop strategies to enhance research effort in rural and remote health in SA. This should be part of a review of the Research Strategy and Policy for SA Health.
16.	Access to relevant private and public data sets for organisations like SANT DataLink and other recognised data linking bodies should be permitted. Such data sets can be restricted for use in HREC approved data-linkage projects that the Department for Health and Wellbeing approves that follow the nationally agreed separation processes to protect privacy.

16.	Relevant legislation should be reviewed to permit access to relevant public and private data sets that have relevance to population health research. This should happen under strict circumstances and with the expressed permission of the Chief Executive of the Department for Health and Wellbeing following positive consideration from a recognised Human Research Ethics Committee. This is particularly relevant to private hospital data sets which currently are not accessible in South Australia. It is noted that this is not the case in NSW and Victoria.
17.	Seek legal opinion about the circumstances that should prevail to permit greater access by University researchers to SA Health patient information systems.

3 Current state analysis

In this report, it is not intended to comment at length on any specific LHN, Human Research Ethics Committee, or other specific ethics or related committees. In general, thematic comments will be made except where there is a specific need to reference either a matter concerning a specific LHN or as the case may be the Department for Health and Wellbeing ethics and research governance processes.

In summary, there is a moderate to high level of dissatisfaction with the current state of affairs in respect to research governance, including ethics approval processes, SSA approval processes and the management of research grant finances. At the WCH there is a high degree of satisfaction with these processes, however at the WCH all funding for governance administration and oversight is drawn from non-operating funds including clinical trial application fees. As such the continuation of the current support for research governance is on a precarious state in so far as its future viability. Elsewhere, (except for a small contribution from operating funds at SALHN, in the Department for Health and Wellbeing and in Country Health SA), clinical trial and research grant application fees are declining, as such the research governance arrangements are somewhat fragile.

In examining the current state, it is not proposed to view a desired future state simply through a lens of universal standardisation for all aspects of governance across sites. Notwithstanding, many aspects of research governance require uniform and standardised processes. This is particularly so when these processes are at the interface with the research grant or clinical trial applicant (who in this instance should be considered “the customer”) or with other institutions where there is a multi-site interface. However, it is acknowledged that under a health system devolved governance regime, it will be up to each LHN to determine the specific organisational arrangements in which site research governance sits and also the level of resources that should be applied to this function.

The principal themes arising from the consultant’s work can be summarised as follows;

Data base and management software

The current research governance data base and tracking software in use in SA is not fit for purpose. It is not user friendly and does not readily generate required reports

with substantial manual work required to achieve satisfactory reporting outcomes. It is used across the health system, however there is a high degree of dissatisfaction with it. Whilst it acts as a database, it does not provide for transparent and open tracking of applications, a function that should be also readily available via pin access to applicants, where they wish to determine progress with their application and any other reporting requirements they are required to comply with. Reporting process times for approval are most likely highly inaccurate in light of the software and also in light of different definitions regarding when the “clock” starts and finishes in the application and approval cycle.

A process is underway in SA to replace the software. This is being centrally led and managed - as it should be. Past experience indicates a poor level of collaboration in this regard between the Department and LHNs. It would appear that at this time (software specification and selection process) collaboration levels are satisfactory however the Department should be the final decision maker in regard to selection. Victoria and Queensland have now moved to new software and NSW is in the process of procuring software. As such it would be sensible to examine their procurements to determine whether compatible or identical software could be procured.

Site Specific Approval (SSA)

The approach to handling SSA approvals across sites is highly variable. As such process times for SSA approval are highly variable. At one LHN SSA average approval times is 70 days. At the same LHN average Human Research Ethics Committee approval times is also about 70 days. This combined cycle time is very long and leads to understandable frustration. This is of course an average and process times as great as 9 months have been cited at some LHNs for some applications. It is acknowledged that some applications are very complex and represent a high degree of risk and potential cost. This is often the case with multi-site studies, however when comparing the WCHN and Bellberry Pty Ltd, it is clear that the current processes in general are unnecessarily risk averse. In a State that claims to be pro research and is seeking investment and commercialisation this is clearly unacceptable. Whilst a detailed analysis of application “drift” has not been undertaken, anecdotal observations suggest that applicants with resources are seeking institutions who can respond quickly to their needs.

It is the consultant’s opinion that

improving SSA approval process time is the single most significant issue facing LHNs and the Department for Health and Wellbeing in respect to research governance. It would also seem that it is the easiest to resolve provided that the commitment to research from the leadership of the Department and the LHNs is strong. If this can be resolved then considerable improvement will be realised. It is noted that at one LHN most SSAs are commenced either at the same time as an ethics application is lodged or where possible beforehand. This seems logical as without corporate approval the application will not proceed and as such an ethics approval is not required. This is not universal practice in South Australia. In addition, one LHN has nominated an Executive level at DCEO rank who has delegated authority to approve SSA's where the cost will be below $10,000 per annum. In addition, it is the responsibility of this Executive to ensure that SSAs where the cost is above $10,000, are not delayed unnecessarily. This is not to imply that they are all approved but rather that a result is obtained quickly. For those where the cost is below $10,000 the response time is 24 to 48 hours for SSA approval.

Resourcing Research Governance Administration

Most LHNs fund research governance secretariats' and associated administration costs from clinical trial grant application fees and more recently some fees levied on research grant applications. Fee revenue is universally declining. In the consultant's opinion, it is not appropriate to levy a fee on research grants in light of the relatively poor state of research grant funding levels. For example, category 1 NH and MRC grants preclude the addition of HREC and SSA costs to NH and MRC grants costs where presumably the NH and MRC believes that this level of infrastructure should be provided by the host institution. It is clear that fees are largely being initiated for revenue raising purposes. The Department for Health and Wellbeing and one LHN provides some operating funding for research governance administration, however this is not significant. There would also appear to be some justification to clearing this matter up in so far as it relates to the relationship between LHNs and the Universities. At the moment Universities receive some infrastructure funding for execution of successful grants. In addition, LHNs through the National Health Funding Agreement on paper receive infrastructure funding, although there is some question as to whether they actually receive the funds via the annual budget process with the Department for Health and Wellbeing.

As such, the question arises as to whether base funding for research governance should be provided from operating

funds. There are a couple of reasons why the consultant believes this should occur. Firstly, a perceived or real conflict of interest exists when all or the majority of funding for research governance is provided through trial application fees. While no evidence of inappropriate practice was found, there is a risk of this happening when the approving organisation is dependent on funding from the applicant in order to support the very process that generates the approval. Secondly, the current arrangements are in a precarious state. It is supposition as to why trial application fee revenue is declining. Anecdotally, based on discussions and observations with a number of interviewees, it would appear that applicants are either seeking approval from sites with relatively short approval process times or seeking approvals through Bellberry (a not for profit approving provider). It may also be that SA is seeing a drop in clinical trials per se, however it is not within the brief of this consultancy to examine this.

The consultant also makes an observation that the State does receive Commonwealth Funding through the National Health Funding Agreement, in part for the purpose of providing some research infrastructure at the LHN level. This is determined by the Independent Hospital Pricing Authority following submission from the Department for Health and Wellbeing. Whilst it was not in the consultant's brief to audit this allocation, it would seem reasonable that some of this funding should be directed to research governance activities in the LHNs and also within the Department for Health and Wellbeing.

It is also recommended that an audit of research infrastructure costs be undertaken in order to determine whether the cost provided to the Independent Hospital Pricing Authority for pricing purposes is accurate and also whether Commonwealth funds received are properly allocated and acquitted. This should then be benchmarked against at least two other States (Victoria and New South Wales is suggested).

Commitment to research

It is reasonable to make an observation about the level of commitment to research at both LHN and Departmental levels. Whilst there are "champions" of research in areas such as research governance and also among many clinicians (particularly clinical researchers) the consultant's subjective assessment is that research (including clinical research) is not considered a high priority at the corporate levels of LHNs. It is understandable in an environment of fiscal austerity that research funding is scrutinized and in particular that

there be a focus on ensuring high quality research which has a high likelihood of clinical translation. However, it does appear that in most areas of the SA Health system (SAHMRI and the Universities being exceptions) that support for research is seen as a cost with little benefit relative to other activities such as patient care and to lesser extent teaching. This may seem a harsh and subjective assessment to some, however it is a general observation that the consultant makes based on his experience and observations within South Australia and at national levels.

A lower priority for funding research infrastructure would be more understandable if SA LHNs were nationally efficient (against the national efficient cost and price) and still could not obtain State funding support for research infrastructure. However, the SA Health system does not compare well with many other States on basic levels of efficiency (cost per NWAU), therefore this absence of research "discretionary" funding seems at odds. Despite better LHN technical efficiency, it appears that Victorian, New South Wales and Queensland LHNs have a significantly greater focus on clinical research (albeit that this is a subjective analysis based on the experiences of the consultant).

As such there would appear to be a few options to address this. Firstly, as previously indicated, it is suggested that an audit is undertaken to determine what are the current levels of research infrastructure funding that is applied to LHNs in SA against the submission made to IHPA which in turn attracts Commonwealth support under the National Health Care Funding Agreement.

Secondly, a couple of simple KPIs should be developed for insertion into LHN and the Departmental for Health and Wellbeing Chief Executive Officer contracts of employment. These could for example be lifted from research KPIs contained within LHN Funding and Service Agreements. These could include the requirement to provide for a base level of research governance infrastructure however, a more important achievement would be a level of NH and MRC or similar funding agency support against the investment made by the LHN and some statement relating to research translation into practice.

Finally, as part of the process to determine the relative role and function of the Department for Health and Wellbeing against that of the LHNs in a "devolved governance" environment, it is suggested that there is a high priority role for the Department to;

1. Develop and maintain a strategy

to maintain and enhance appropriate and relevant research in SA Health funding agencies;

2. Develop, maintain and monitor appropriate state-wide KPIs for research to be reported on annually and included in the assessment of LHN overall performance;
3. Develop and maintain a whole of Department policy for research which should include requirements for standard and consistent approaches and methodologies for research governance (including all ethics and SSA approvals) within the Department and in LHNs;
4. Take ownership of and maintain a supporting database and tracking software that should be mandated for use across all health agencies. This should also include the development of a state-wide portal as a single access point for all research grant and clinical trial applications. This is similar to what happens in Victoria. It should be noted that the portal acts as a "distribution warehouse" with LHN and Departmental Ethics Committees still maintaining the approving function;
5. Own the "master" for all forms relating to ethics and related approvals.

The above five initiatives will require some additional staffing and resources at the Departmental level. It is suggested that the responsibility for these staff and resources be placed under the auspices of the Chief Medical Officer's (CMO) Division. It is also suggested that a Director of Research position should also be created, reporting to the CMO. Additional resources should not result in a net cost increase to the Department in light of the process to streamline administration and reduce bureaucratic overlap elsewhere between LHNs and the Department. It is assumed that this can be funded through the budget reallocation process. A possible mechanism for funding the roles of both the central agency (the Department) and the LHNs is to top slice the allocation from the National Health Funding Agreement relating to research.

It is the consultant's opinion that a failure to more adequately support research through some of the mechanisms indicated here will almost certainly increase the difficultly in maintaining a highly capable clinical workforce and in stimulating a level of innovation, which is all the more important in an increasingly competitive environment within health care.

Standards and Processes

There are a range of other “standards” that should be determined at a state-wide level and managed locally. These include the appointment of state-wide expert panels and individuals who have unique specialist skills that are not easily replicated across LHN ethics and related committees. Some examples might include data linking, genomics, gene technology and highly specialised areas of science and medicine that do not require frequent reference to specialist skills. This also could include Aboriginal and Torres Strait Islander Health. In the case of data linking it would seem logical to leverage the considerable expertise that exists within the Department for Health and Wellbeing research governance secretariat and Ethics Committee for whole of State needs.

Another such area is the development of common definitions and approaches as to what constitutes low, medium and high-risk applications for ethics approval assessment. There appears to be considerable variation of approach between LHNs and this inevitably leads to confusion amongst applicants and unnecessary delay in achieving approval particularly in the event that an application is low risk. Bellberry Ltd offers training as a consultancy in this regard and it is suggested that this is taken up across South Australia to achieve a high level of application assessment consistency.

A further area for consideration is the need for specific guidance regarding acceptable practices in delivering research “activities”. For the researchers, it is the process as well as the end result that is important.

An example provided to the consultant is as follows;

In approaching women on hospital postnatal wards for the same or similar studies there are three different ways researchers are asked to do this as non-employees of the LHNs e.g.; University employees.

1. They need to check with the charge nurse about who is appropriate to approach and the research nurse goes ahead or;
2. They need to check with the charge nurse about who is appropriate to approach and then one of the LHN staff need to get a verbal consent from the woman that it is in order to talk with a researcher or;
3. They need to check with the charge nurse about who is appropriate to approach and then one of the LHN staff need to get a written consent from the woman that it is in order to talk with a researcher about the particular project.

This demonstrates a high degree of

variability and justifiably increases frustration among researchers. Clearly there is a need to protect patient privacy but the third option has no doubt proven too obstructive to research processes both in terms of cost and erosion of good will with hospital staff, without significantly enhancing privacy protection.

Another area concerns ethics approval for phase 1 studies. To undertake a phase 1 study in South Australia an applicant is required to submit to a SA Health based HREC. If the applicant is the sponsor and they wish to select sites and 95% are on the eastern seaboard they can do one HREC submission for them and then if the applicant wishes to come to SA, a further submission to a HREC here is required (only CALHN and WCHN are certified for phase 1 review). Comparatively, if the study were phase 2 the lead HREC could be on the eastern seaboard and this is considered to be an acceptable approval.

In light of the fact that the majority of phase 1 trials would be conducted on the eastern seaboard, it seems reasonable to simply accept the ethical review obtained elsewhere. It is simply not an attractive proposition for South Australian researchers to be the sponsor if the sponsor has to wait (and pay) for another ethical review. It would be cheaper (and quicker) to pick another site on the eastern seaboard that accepts the review.

There are many other case examples cited regarding process and approval variability including impacts at the clinical coal-face that undermine effective clinical trial and research activities.

Bellberry Pty Ltd

Bellberry Pty Ltd is a private, independent and not for profit organisation founded over 10 years ago. It's stated purpose is in "protecting the welfare of human research participants and improving the quality, efficiency and effectiveness of research in Australia". It has a number of Human Research Ethics Committees that are all NH and MRC certified. There are eight committees based in Adelaide and Queensland with a pool of 100 committee members. Bellberry levy fees on applicants who are seeking ethics approval. SSA approvals remain the province of respective LHNs although no State or Territory currently offers Bellberry national mutual acceptance for its ethics review decisions.

Bellberry claim to have a strong focus on quality and timeliness of review with a running average of approximately 20 days turnaround from study submission to review decision. WCHLHN compares favourably to Bellberry performance, however no other LHN matches this level of performance.

Some of the features of Bellberry's operations include the following;

- An electronic submission process with an ability for multi-site investigators, researchers and institutions to interact virtually via a portal;
- A robust pre-submission triage

process;
- A frequent calendar entry point to the process whereby submission closing dates occur weekly;
- A training, development and auditing consultancy capability.

Notwithstanding NH and MRC compliance, it is the consultant's understanding that national mutual acceptance approval is not provided to Bellberry by any State or Territory. It is not clear why this is so other than some commentary about whether the robustness of Bellberry's processes are equal to that of State and Territory funded ethics committees. The consultant did not undertake a rigorous review and comparison between Bellberry and publically administered Ethics Committees. However, it is difficult to accept the proposition that Bellberry do not provide high quality assessments. It is also a concern that in South Australia almost all the funds required to support ethics committees are generated from application fees.

As such it is the view of the consultant that the current state of affairs is somewhat "protectionist". As such there seems no reason why approvals obtained through Bellberry should not be subject to national mutual acceptance equivalence by South Australian entities. This should not pose a threat to LHNs should the recommendation for base funding of research governance be agreed. In addition, SSA approvals will still be required and these are administered by the LHNs and the Department for Health and Wellbeing. It is noted that NMA for Bellberry approvals is not likely from interstate public entities, in which case this recommendation may only be applicable to SA State based research.

Data and access to SA Health IT systems

There are a number of issues concerning access to health data, unrelated to the consultant's brief that were raised during the consultancy. In the consultant's opinion, they warrant further consideration as they of significant concern to researchers in South Australia and the advancement of research, particularly requiring the use of population health data sets. The issues and suggestions can be summarised as follows;

- South Australia needs to take an all of system, population-based approach to data collection, analysis and feedback to services. NSW and Victoria have already moved in this way. Support for broader approaches comes from organisations like the Australian Commission on Safety and Quality in Health Care (ACSQHC), various privacy bodies, the Australian Health Ethics Committee and the Australian Institute of Health and Welfare (AIHW).
- Access to relevant private and public data sets for organisations like SANT DataLink and other recognised data linking bodies should be permitted. Such data sets can be restricted for use in HREC approved data-linkage projects that the Department for Health and Wellbeing approves. These should follow the nationally agreed separation processes to protect privacy. By way of example, NSW and Victoria already have access to private hospital data and whilst they do not ask private hospitals for explicit permission for use of data, they do advise all private

hospitals that access is occurring and that data can only be released which would not allow individual private hospitals to be identified directly or by inference.

- South Australia is faced with a circumstance where key private hospitals will not permit linkage keys to be established by SANT DataLink as the current legislation in South Australia does not permit this as a condition of private hospital licencing and registration. This should change and it is suggested that the relevant legislation is reviewed to permit this to happen under strict circumstances and with the expressed permission of the Chief Executive of the Department for Health and Wellbeing following positive consideration of a recognised Human Research Ethics Committee.

Management of research funds

Some interviewees raised the challenges faced in gaining access to funds awarded to them through research grants processes. In some LHNs (it may be all LHNs however the consultant did not confirm this) funds awarded are administered by Research Governance Secretariats through specific purpose funds accounts (SPFs). The complaint made was in regard to alleged unnecessary bureaucracy and inadequate delegations to the principal investigator.

It has not been possible to verify these claims however it is suggested that delegation levels be reviewed (to determine “fit for purpose”) by all LHNs. Some interviewees suggested that control of SPFs should not reside with Research Governance Secretariats’, however the consultant does not agree with this given the considerable difficulties that have occurred in past years with financial acquittals for SPFs.

Department for Health and Wellbeing Human Research Ethics processes

Some interviewees expressed frustration with the Department for Health and Wellbeing HREC processes and process times for approval of applications. It was felt by some that the HREC was at times also reviewing the merit of the research in addition as to whether the research warranted ethical approval. It is the view of the consultant that at times some consideration of research merit is justified in order to adequately assess whether it is ethical. However, this should not be the norm.

It is noted that some applications to the Department HREC may not require their consideration. These may include nationally sanctioned studies which have legislative coverage or where agreement has been reached by jurisdictions to proceed. These may be considered low risk and could either avoid consideration by a HREC or at the very least be approved out of session.

In any case, should other recommendations be implemented pertaining to research governance, it is likely that process times and better segregation of risk categories may occur.

General Observations

There are a number of other observations the consultant has made. However, these are somewhat unrelated to the brief. As such they will only briefly be mentioned;

- There appears to be a low level of support for research into rural and remote health in South Australia despite the considerable opportunities and funding that exists at a national level. Research governance is administered by Country Health SA through the allocation of a part-time resource. Ethics Committees from other LHNs and the Department are leveraged for assessment of applications pertaining to Country Health sites. It would seem timely to develop a robust research and development strategy as there would appear to be an opportunity to enhance research and leverage national funding streams.
- There is a high level of dissatisfaction with the current state of affairs with LHN research governance and support for research from some universities and also SAHMRI. The University of Adelaide is particularly frustrated with cycle time responses for application approval and variability in approach between LHNs. This is also the case with SAHMRI. Flinders University has a closer relationship with SALHN although there is the opportunity for greater cross membership between relevant FUSA and SALHN ethics committees.
- A further major issue for Universities is the inability to obtain satisfactory access for University staff to SA Health patient information systems. It is suggested that legal opinion be obtained to determine the circumstances where this could be facilitated. Such circumstances might include (but not be limited to);
    - Limited access to researchers for specific purposes and with appropriate HREC approval;
    - A written agreement between the University and SA Health about adherence to SA Health policies and a mirroring of code of conduct requirements;
    - Monitoring and auditing requirements.
- The issue of intellectual property also was raised frequently during interviews. This probably warrants a separate examination. IP assessment and management is a very specialised skill. As such it is unlikely that the skill sets required for general research governance are not the same as for IP management.

4 Victorian Comparison

In undertaking this consultancy, it was agreed that at least one other site should be examined to make a comparison with South Australia. In this instance, it was decided to examine Monash Health. This examination was done in the context of Monash as part of the wider Victorian public health system. A detailed current state documentation review and analysis was not undertaken, rather a literature review and interviews with relevant people at Monash was conducted. As such, the objective was to determine whether there are any areas of learning and opportunity for South Australia.

Victoria has invested in overarching governance support and infrastructure beyond that which exist specifically at the LHN level. At the Departmental level, there is a Coordinating Office for Clinical Trial Research and other expertise in the Department focussed on health and medical research policy. It is important to understand the context of Victoria relative to South Australia. Firstly, the population size exemplifies this when one considers that Monash Health covers the health needs of a population of approximately 1.8 million (and growing). In addition, the size of the research industry is substantially greater than in South Australia. As such there is a natural competitive tension that exists between LHNs and there appears to be a very strong motivation for streamlining processes, thereby achieving productive cycle times for SSA and HREC approvals.

This makes the imperative for South Australia to be even more efficient and stream-lined. Many of the observations contained in this section have already been factored into the current state analysis in section three of this report and in framing the recommendations in section two. The thematic observations made by the consultant for Monash Health and Victoria in general are as follows;

- There is constructive and a relatively well-resourced oversight from the Department of Health and Human Services in respect to a framework, infrastructure and standard approaches for research governance in Victoria. This extends to a new website called ERM (Ethical Review Manager) which was launched in July. This website is for applications in the Victorian and Queensland health systems.
- There are standard forms and strong encouragement for standard processes for LHNs who administer research and in particular HRECs and other ethics and related committees.
- A health.vic website includes substantial materials for use by LHN research governance secretariats and units. This covers such areas as;
    - Various agreements applicable to trials and grant applications.
    - Research governance guidance and suggested site-specific processes.
    - A list of participating organisations.
    - A calendar of reviewing Human Research Ethics Committees by each site, dates of meetings and a list of responsible officers.

- An area for applicants to assist in their endeavours to generate a high-quality application.

- At Monash;

  - There is strong encouragement to commence SSAs before HREC assessment.
  - The time for approval of SSA and HREC approval varies considerably based on the level of complexity and risk. This is the same in South Australia. However, the stated average elapsed time is 12 weeks. Verification of this was not undertaken however if this is the case then it is considerably better than most South Australian sites. It appears that there is considerable effort to keep cycle times reasonable. Processes such as Chair decision making delegation for low risk applications and HREC approval subject to conditions being subsequently approved out of session, are used frequently. The consultant sighted a presentation from Quintiles which included similar cycle times. Accordingly, an average of 12 – 20 weeks would appear feasible, however it is noted that valid and comparable data is difficult to access.
  - It appears that clinical trials are prioritised. This is on the basis that it generally entails clinical care for people and also there seems to be a desire to create a commercially attractive environment.
  - It was noted that there is a State-wide focus on leveraging groups and individuals with very specialised expertise. Examples in this instance included data and data linking, genomics and infectious diseases.
  - Monash University leverages the Monash Health HREC process and approvals. There is a memorandum of understanding and it would appear all the risk rests with Monash Health. This seems to be readily accepted.
  - Other observations included;
    - Rapid response times for SSA signatories to approve
    - Single point of contact for budget negotiations
    - Agreement on standard costs
    - Clear delegation arrangements

- An interesting and informative presentation was obtained titled “The Paperless Committee”. This was authored by Simon Barrett, Deputy Director Monash Research Office. It is attached as Appendix 2. It covers the areas of biosafety and biosecurity, human ethics and animal ethics. It presents the case for the Victorian ERM system. It certainly presents a compelling case for a State-wide, high quality research governance information system. There are considerable benefits outlined for researchers, Ethics Committee members, research governance officers and the corporate services of LHNs and the Department. Rather than list these here, the presentation warrants consideration from readers of this report.

As indicated earlier in this section, a comprehensive and detailed analysis of the Victorian research governance system

and processes was not undertaken. However, the key takeaway messages are;

- Robust and effective information system support applied across the whole of the health system.
- A culture of research enhancement and support where the health and commercial benefits of research and clinical trials seem to be front and centre.
- Positive and effective support and oversight from the Department in respect to policy, performance, standard forms and processes.

Bibliography

(1) Research Governance Policy Directive; Version No: 3.1; SA Department of Health and Ageing, 13th November 2017

(2) Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the Sector; MTP Connect; June 2017

(3) Research Focus 2020 – Our Strategic Priorities; Department of Health and Ageing; August 2017

Please note that there were many other documents accessed in respect to research and research governance. However, these were not specifically cited in the report.

Appendix 1 – List of interviewees

Name	Title	Department/Organisation
Philip Robinson	Executive Director, Corporate Services	Women's and Children's Health LHN (WCHLHN)
Helen Marshall	Deputy Director, Robinson Research Institute	WCHLHN
Andrea Averis	Director, Research Secretariat	WCHLHN
Camilla Liddy	Research Governance Officer	WCHLHN
Maria Makrides	Deputy Director	SAHMRI
Sarah Robertson	Director, Robinson Research Institute	University of Adelaide
Tamara Zutlevics		WCHLHN
Alison Barr	Research Governance Officer	Northern Adelaide ALHN
Alastair Burt	Executive Dean, Faculty of Health and Medical Sciences	University of Adelaide
Andrew Zannettino	Professor of Experimental Haematology	University of Adelaide
Simon Brennan	Executive Director, Research Services	University of Adelaide
Tony Cambareri	Research Development Manager	University of Adelaide

Name	Title	Department/Organisation
Steve Wesselingh	Chief Executive	SAHMRI
Stephen Nicholls	Deputy Director	SAHMRI
Bernadette Swart	Manager, Research Office	Central Adelaide LHN
Don Mackie	Executive Director, Medical Services	Central Adelaide LHN
John Beltrame	Professor of Medicine	University of Adelaide
Katina D'Onise	Public Health Physician	Department of Health and Wellbeing
Sue O'Neill	Chief Executive Officer	Southern Adelaide LHN
Carmela Sergi	Health Partnerships Director	Flinders University
Robert Saint	Deputy Vice Chancellor, Research	Flinders University
Ross McKinnon	Dean, Research	Flinders University
Jodiann Dawe	Director, Research Development and Support	Flinders University
Marc Davies	Associate Director, Legal and Risk	Flinders University
Andrea Church		Country Health SA LHN
Hendrika Meyer	Executive Director, Medical Services	Country Health SA LHN
Paula Davies	Assistant Director, Office for Research	Southern Adelaide LHN
Andrew Bersten	Director of ICCU	Southern Adelaide LHN

Name	Title	Department/Organisation
Simon Windsor	Research Governance Officer	Southern Adelaide LHN
Erwin Loh	Chief Medical Officer	Monash Health
Stephen Holdsworth	Professor of Medicine	Monash Health
Deborah Dell	Manager, Human Research Ethics	Monash Health
Kylie Sproston	Chief Executive Officer	Bellberry Pty Ltd
David Roder	Beat Cancer Research Chair	University of South Australia
Hugh Grantham	Professor of Paramedics	Flinders University
Melane Thorrowgood	Clinical Audit and Research Manager	SAAS
Richard Larsen	Operations Manager	SAAS
Shaun Berg	Lawyer	Berg Lawyers
Alison Jones	Director, Medical Education and Research	Department of Health and Wellbeing
Melissa Kluge	Research Ethics and Policy Officer	Department for Health and Wellbeing
Paddy Phillips	Chief Medical Officer	Department for Health and Wellbeing
David Vanderhoek	Senior Policy Officer	Department for Health and Wellbeing

Appendix 2 – The Paperless Committee – Simon Barrett, Deputy Director, Monash Research Office

Refer attached