Special Commission of Inquiry into Healthcare Funding

Statement of Professor Christopher Levi

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1. This statement made by me accurately sets out the evidence that I would be prepared, if necessary to give to the Special Commission of Inquiry into Healthcare Funding (**the Inquiry**) as a witness. The statement is true to the best of my knowledge and belief.

2. It is provided in response to topics identified by the Inquiry in a letter to the Crown Solicitor's Office dated 14 August 2024 (MOH.0010.0542.0001), to the extent that such topics are relevant to my role, and to the Inquiry's letter to the Crown Solicitor's Office dated 22 August 2024 (MOH.0010.0541.0001).

A. INTRODUCTION

3. I am the Executive Director, Research and Innovation, at Hunter New England Local Health District (HNELHD) and I am also a practicing Senior Staff Specialist neurologist at John Hunter Hospital (JHH). I addition I hold the following HNELHD roles:

    a. Chief Clinical Information Officer,

    b. Director, John Hunter Health and Innovation Precinct,

    c. Co-Director Hunter New England Sports Concussion Clinic,

    d. Director, Rural, Regional and Remote Clinical Trials Northern Cluster.

4. I am a Conjoint Professor of Medicine at the University of Newcastle, a Fellow of the Royal Australian College of Physicians and a Board Director of the Hunter Medical Research Institute. My achievements in stroke research have been recognised by the award of fellowship of the Australian Academy of Health and Medical Sciences.

5. In my role as Executive Director, Research and Innovation, I am responsible for leading Research and Innovation strategy and operations that aims to support and enable a "learning health system" model in the District. The role also involves building on and establishing new academic and industry partnerships underpinning the new John Hunter Health and Innovation Precinct and leading the Northern Cluster (Hunter New

England, Mid North Coast, North Coast and Central Coast) NSW Regional Rural and Remote clinical trials enablement project. As Chief Clinical Information Officer I am responsible for change management and implementation of HNELHD's digital health transformation strategy including the Single Digital Patient Record preparedness and upcoming rollout.

6. In my role as Senior Staff Specialist, I continue to provide frontline clinical stroke care to the Hunter New England, and cross-District care to patients from the Central Coast and Mid North Coast catchments. I established HNELHD's Acute and Interventional stroke services (until recently the only regional interventional neurology service in Australia) and established and validated the model for tele-stroke services supported by advanced CT brain imaging, a model of care successfully scaled-up across NSW.

7. I am now beginning to scale down my personal research portfolio, however, continue to lead a number of National Health and Medical Research Council (**NHMRC**) and Medical Research Future Fund (**MRFF**) grant funded clinical trial projects in acute stroke and stroke recovery (including the development of novel stroke recovery intervention for Aboriginal stroke survivors). I continue to supervise research higher degree candidates and provide mentoring support to my mid-career colleagues stepping into clinical academic leadership roles.

8. A copy of my curriculum vitae is exhibited (MOH.0010.0634.0001).

B. CLINICAL TRIALS USING A LOCOREGIONAL STRUCTURE

Background

9. Clinical trials offer patients early access to new treatments. They equip practitioners with new skills and provide diversity of experience and enhanced job satisfaction. They bring economic benefits, staff attraction and retention advantages, scientific advancements and potential commercial benefits to the clinical trial provider. However, there is a lack of access to clinical trials in regional, rural and remote areas. As a result, populations in these areas lack access to innovative therapies and trials addressing the particular health needs of these populations are rare. Barriers to regional clinical trials have included lack of clinical key opinion leaders to attract trials activity, lack of workforce skills and capacity and consequent lack of attractiveness to both the academic and commercial sector sponsors.

10. The Ministry of Health Office for Health and Medical Research (**OHMR**) was established in 2011 to build research capability in NSW. ClinicaltrialsNSW is an initiative of the OHMR to enable clinical trial capacity, capability and collaboration across NSW and provide equity of access to innovative healthcare to NSW communities.

11. In 2021 ClinicaltrialsNSW sought funding from the Commonwealth Government's MRFF for a project plan titled *Bringing Clinical Trials to the Bush – improving access to innovative healthcare in rural, regional and remote NSW and ACT,* exhibited (MOH.0010.0657.0001)**.**

12. The MRFF granted funding for the project plan under the 2019 MRFF National Critical Infrastructure Initiative – Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant. The proposal became the NSW Rural, Regional and Remote Clinical Trial Program (**R3 CT Program**).

13. Approximately $30 million granted by the Commonwealth has been allocated by the Ministry of Health (**MOH**) to be distributed under the R3 CT program.

14. The R3 CT Program is managed by OHMR through clinicaltrialsNSW. A key activity of the program is the establishment of a locoregional network of three regional, rural, and remote clinical trial support units (**R3CTSUs**) covering all LHDs and ACT health services covering Modified Monash Model 3-7 populations. The R3CTSUs provide clinical trial support to each cluster through, broadly speaking, the establishment of a "hub and spoke" support unit within clusters.

15. Commenting more specifically on the Northern cluster, overall cluster leadership and management across domains is centralised and delivered virtually. These roles and skills are generic and relevant across each partner LHD hence, not economically appropriate to replicate in each LHD. The central services domains include:

    a. clinical trials business development and attraction,

    b. communication and marketing of the cluster assets,

    c. finance management,

    d. discipline specific clinician network support,

    e. generic education training and

    f. generic/standardised operational activities.

16. Front-line clinical trials recruitment and coordination support and the local leadership and management of the clinically embedded trial support workforce is de-centralised and locally delivered within each of the key referral hospitals in the cluster.

17. The key roles for the centralised services are attracting business and supporting the embedded front-line coordination staff to operationalise the trials that are identified and progressed. Typically, the central service support covers (in close collaboration with the hospital recruitment sites):

    a. scouting the trial opportunities,

    b. protocol reviews,

    c. site feasibility assessment,

    d. budget build-ups (using a validated budgeting tool),

    e. supporting the site teams in ethics and governance approval and

    f. contract finalisation.

18. Locoregional stakeholders are engaged throughout this process but then take carriage of activation and recruitment. Clinical trials remuneration is generally via a per patient payment model and a revenue sharing model is currently in development aiming for financial return that will be sufficient to maintain and sustain both the central services and the locoregional coordination workforce by January 2027.

19. NSW Health has supported the establishment of the three locoregional clusters, covering the northern, western, and southern NSW/ACT region. The locoregional cluster structure is guided by a collaborative agreement between each of the LHDs in the cluster. Each cluster may then apply to OHMR for funding of up to $6million over a four year period. The balance of the MRFF grant, being $18million, is managed centrally by OHMR.

Northern Cluster

20. I am the director of the Northern Cluster R3 Network and have significant experience in the running of clinical trials.

21. Part of my role is to ensure that the Northern Cluster R3 Network becomes financially sustainable by late 2026 given the funding horizon for the Commonwealth grant is January 2027. This will require attracting sufficient commercial and academic sector trial activity, hence business attraction is a critical activity at this point in the

programme. Financial modelling suggests that the Northern cluster will be required to have somewhere in the order of 25-30 clinical trials under management by 2026 and that around 50% of these trials will need to be well funded commercially sponsored trials in order to cover central and locoregional support service workforce and operational costs.

22. There are four broad domains which I consider necessary for success and financial sustainability of the cluster's clinical trial program:

    a. Growing the clinical trials portfolio including, *inter alia*, increasing the number of clinical trials (in particular commercially sponsored trials), increasing the range of therapeutic areas in which trials are conducted, increasing community awareness of clinical trials and the number of participants involved in trials and increasing the range of trial delivery methods,

    b. Developing a minimum viable central support service model and a financial management structure, to increase the return on investment for clinical trials and the value proposition of the trial portfolio for the health system and for sponsors,

    c. Business attraction management, being able to interface with sponsors to bring business in; and

    d. Supporting quality conduct of clinical trials, being the ability to deliver on total quality management system for clinical trials. The Australian Commission for Safety and Quality in Healthcare National Clinical Trials accreditation program is now underway and, for our regional referral hospitals to gain accreditation and remain viable clinical trials site, hospitals will be required to have in place the adequate capability in trials management, quality assurance, monitoring and audit. The R3 central services team are working closely with our locoregional teams to prepare for this program.

23. The $6 million of funding provided to the Northern Cluster R3 Network is intended to cover each of the above domains, with the central funding retained by OHMR used to support the needs and issued raised by each cluster. At the inception of the programme, OHMR established a number of working groups under what was termed "key activity areas". The retained central funding was to support activities of these working groups. Broadly speaking, and recognised by OHMR, the productivity of these working groups has been limited. A tangible return on investment from the OHMR central funding has been disappointing. The most pressing example of the limited

productivity and limited support for the clusters is in the lack of progress on the development of online business attraction and promotion support. This includes limited activity in the development of promotional websites for the clusters, online prospectus', social media connections to support business development, along with a lack of appropriate community and consumer facing information. This relative "invisibility" to the potential clients, and to the patients and the public in has caused considerable frustration for cluster leadership. Limited productivity in other domains including progress on engagement with community and consumer advocacy groups, establishment of access for the clusters to generic education training assets, has also raised questions about the value of this centrally held funding. Efforts by the Northern cluster to develop a website and social media presence for business attraction have not been supported.

24. At the moment, the Northern Cluster R3 Network has approximately 12 trials, with 2 being commercially supported. However, the cluster faces limitations arising from the lack of visibility of the clinical trials opportunities and capabilities in our regional areas, partly related to the lack of online and social media presence necessary to raise the awareness of capability with sponsors and to raise awareness with the community of clinical trials under management.. This need presently remains unmet and appears to be at least partly a result of the shift of all NSW Government web communications to the OneCX Program, which is managed centrally, preventing bespoke versions of online communications for each LHD/cluster being developed.

25. There is currently tension between OHMR and clusters surrounding the productivity of the central working groups and the risk that poses for the clusters in the delivery and sustainability of the current clinical trial enterprise. Some of this tension relates to matters of administration and the limited responsiveness to needs such as those outlined above, but also to the $12 million of funding held centrally by OHMR while there are unsupported needs in the clusters could be addressed by access to such funding. In addition to the concerns regarding tangible outcomes supporting business attraction, community and consumer awareness and involvement, and assembly of relevant education and training assets for the clusters, all clusters are concerned that within a 2-year timeframe, they will be required to be generating operating profit margin of somewhere in the order of $1-$1.2 million per annum in order to sustain their central and locoregional workforce and operations. There seems to be limited awareness of the significant challenge posed by this requirement. The limited central support in

establishment and growth of the trials business leaves the clusters feeling somewhat isolated and exposed to risk of nonviability at the end of the Commonwealth funding.

26. In addition to the work being done by the Northern Cluster R3 Network, HNELHD is also currently looking at our own initiative is in public and patient involvement in clinical trials and research more broadly. This will involve promoting the capabilities of our regional hospitals in clinical trials delivery via our Local Health Committees across the District. We anticipate that this will lead to increased community awareness of the opportunities for greater promotion and involvement in clinical trials for the rural and regional patients.

C. OTHER USES OF LOCOREGIONAL STRUCTURES

The Diabetes Alliance Program +

27. The Diabetes Alliance Program (**DAP**) began in 2015 as a partnership between HNELHD and the Hunter New England and Central Coast Primary Health Network (**PHN**) and transitioned from a pilot program in 2015 to business as usual in 2017.
28. In 2023 the Diabetes Alliance Program Initiative expanded to become the Diabetes Alliance Program Plus (**DAP+**), joining Hunter Medical Research Institute and the University of Newcastle to the collaboration.

29. DAP+ aims to improve health outcomes and the experience of care for patients with diabetes within their own local general practice by offering a range of flexible services, including in-person case conferencing clinics between the DAP+ specialist team, the local general practitioner and patient, as well as telehealth services to help eliminate access and transport difficulties for patients.

30. DAP is a shining example of a highly effective model of care the brings together specialist diabetes management and primary care providers in a model that up skills and empowers the primary care practitioners, provides them with direct and virtual access to the specialist expertise they need, and wraps around the model of care, a sophisticated audit and quality improvement program. The results from this model of care have been outstanding in terms of improvements in diabetes management across over 100 general practices in the region. The addition of translational research and innovation to the model of care in partnership with HMRI, University of Newcastle and funded by a $10 million grant from the Colonial Foundation, will allow exploration and evaluation of novel elements supporting healthy ageing, dietary and exercise intervention, including satellite enabled mobile clinical care delivered via the diabetes Medibus.

31. The DAP model that combines the efforts of PHNs and LHDs around a chronic complex disease is a model which could be applied to the management of other chronic diseases such as mental health conditions, cardiovascular diseases and stroke, chronic respiratory diseases, or broader primary prevention at a public health level. This merger of efforts that integrates specialist knowledge and services into locally based primary care has proven its benefit in diabetes and should be considered for proof of concept evaluation in other chronic disease and public health domains.

32. The NSW Telestroke Service is a collaboration between the Prince of Wales Hospital in Sydney, eHealth NSW, the Agency for Clinical Innovation (**ACI**) and MOH which connects 23 rural and regional hospitals across NSW with a network of virtual specialist stroke doctors, managed by the Prince of Wales Hospital. It aims to provide people across NSW with rapid virtual access to specialist stroke diagnosis and treatment. It helps local emergency physicians connect with expert stroke clinicians to determine the most appropriate treatment for each patient.

33. This service had its genesis in the HNELHD Stroke Service. The initial research and model of care developed in HNELHD has been successfully rolled out as a statewide service in 2019. Although there has been significant benefit in offering this model as a statewide service, as the service has become (in the view of many of the clinical academic neurologists) overly centralised, too detached from our local referring regional centres. The driving force behind the services inception, research, and innovation, has withered and is now not a priority within the current service model. A number of research active neurologists have attempted to engage with the statewide service without success. In reality, high performing comprehensive stroke centres can provide a more efficient and effective service to our referring regional centres and have the capability and capacity to continue to push forward with research and innovation. The centralised service and the "middle-man" model, although arguably required at inception, is now an impediment to innovation, improvement and research which are all geared up to occur in a locoregional model. A recent review of the service showed 3-month good functional recovery rate of only 36%. This rate is relatively low in proportion to established benchmarks, with a reasonable expectation of at least 50% good functional outcome rate in this patient population. Further, the complication rate of major brain bleeding after intravenous thrombolysis was 6% which is approximately double international benchmarks. From my discussions with the stroke neurology community there are concerns that the service is not sufficiently focussed on this. In

my view, the service needs to continue to evolve to re-embrace research and innovation.

34. This evolution will require the authorising environment to consider reform with potentially the establishment and evaluation of a new hybrid model where central coordination and telehealth infrastructure services are maintained, but where clinical care delivery is delivered via the comprehensive stroke centres based in Sydney and in Newcastle. Equitable statewide coverage for endovascular stroke therapy would then, subsequently require the establishment of a comprehensive stroke centre in Wollongong providing interventional stroke services to the Illawarra and South Coast, much in the same way as John Hunter Hospital is able to provide comprehensive stroke care to Hunter New England and the North Coast of NSW. The delivery of time critical therapies such as endovascular stroke should not all be centralised in Sydney, noting, of course the need for balance between equity of timely access to treatment and the feasibility and cost effectiveness of establishing a new service.

35. A reform in the current model of care would allow comprehensive stroke centres and their clinical workforce to support their referral hospital catchments, provide direct care (without the need for a third-party interface between the referring hospital and the comprehensive stroke centre) and reactivate the innovation and research that will be necessary to evolve and improve the model into the future. Some degree of de-centralisation in advanced methods of care such as stroke reperfusion, would also enhance workforce attraction retention in our regional hospitals. Finally, a hybrid model where the comprehensive stroke centre provides clinical telestroke care as part of its "business as usual" would improve the cost effectiveness of telestroke care where the medical staff payments supporting the centralised workforce are significantly above what would generally be regarded as a reasonable and appropriate reimbursement for services rendered.

D. INNOVATION

36. The February 2023 integration of the Agency of Clinical Innovation (**ACI**) and OHMR into the new Division of Clinical Innovation and Research (the **CIR Division**) of MOH has been a welcome development to support innovation in NSW Health.

37. Another positive development is NSW Health's $835 million John Hunter Health and Innovation Precinct project (**JHHIP**). This will deliver a new seven-storey Acute Services Building, refurbishments to some of the existing facilities, and other

infrastructure works including improvements to internal roads, landscaping, wayfinding, engineering, and ICT services.

38. It aims to deliver an innovative and integrated precinct with industry-leading facilities, working in collaboration with health, education, and research partners to meet the current and future needs of the greater Newcastle, Hunter New England and northern NSW regions. The JHHIP is primarily regionally focused, with a mission to address regional and rural unmet needs across domains of

    a. healthcare logistics and models of care,

    b. digital health,

    c. health technology advancement (with a particular point of care technology), and

    d. regional healthcare sustainability.

39. The JHHIP is fortunate in being able to build on an existing strong foundation of academic partnership with the University of Newcastle (**UoN**) and the Hunter Medical Research Institute and is expanding under the guidance of the JHHIP Precinct Council where the partnership has governance representation from the Division of Research and Innovation, Health Infrastructure, and the commercial sector.

40. The Precinct Council has approved establishment of a partnership fund of $1 million per year that will provide investment to support innovation project activity across the four domains. Initially this project activity will be focused around the location of the John Hunter Hospital and the Health Innovation Living Laboratory, (the HILL), a new HNELHD and UoN co-funded facility established in 2023 and now operational, bringing together academic and commercial sector innovators, clinical entrepreneurs, clinicians, and managers to co-lead innovation projects.

41. The HILL now has embedded industry in academic teams as well as the HNELHD biomedical engineering 3D printing facility and our knowledge brokering and librarian services. Innovation project activity is priority driven and project activity currently includes the establishment of a Medibus fleet to enable rural and remote care delivery including satellite enabled virtual care services, exploration of AI enabled hospital capacity management solutions, and the adaption of virtual reality technology to clinical settings to improve the quality and safety of clinical workflows.

42. A primary challenge remains, however, in the balancing of adapting to evolving technologies and adopting innovation against the procurement and funding required to

support innovation. The central agencies and authorising environments governing procurement and regulating finance, are generally not innovation permissive. Current "safeguards" around deployment of public funding often prevent timely access to innovative technologies. Given the increasing challenges facing the health care delivery sector, Chief Executives, Chief Financial Officers and Executives in Operations need to have the ability to engage with new technology, and in particular the increasing opportunity in AI enabled digital health, in a way that allows LHDs to minimise their exposure to risk, maximise probity, but still move forward and ideally move at pace to road-test certain innovations in a "prove fast or disprove fast" model. This is in part, the rationale for the establishment of the Health Innovation Living Laboratory at John Hunter Hospital.

43. There also needs to be a shift in investment in health technology, evaluating the ability to implement new health technologies, rather than focusing on the most financially affordable option. For example, I have been working on an evaluation of light weight, portable stroke detectors in Ambulance service vehicles, however, due to current procurement pipelines, I am aware that should such technology is receive TGA registration it would take up to 3 years for such technology to navigate the process to approval for implementation.

44. Another area of innovation that could support optimal hospital access would be the implementation of computational machine intelligence enabled capacity management and associated so-called "command centres". International evidence indicates that hospitals adopting AI decision assistance to support patient flow decision demonstrate clear advantages over the traditional operational models. Given many of our regional hospitals are often at 100% bed occupancy, however, LHDs face multiple challenges in developing commercial partnerships and then managing those partnerships to the point where solutions are locally tested to reach the "proof of concept" level, such that the solution could then be propose for serious conversations around adoption and scale up. In my view, the NSW Health has a significant opportunity to make use of the innovation precincts and their academic partners to undertake rapid evaluations of new technology. Again this is partly the rationale for the establishment, in partnership with University of Newcastle and the HMRI, the Health Innovation Living Laboratory at John Hunter Hospital.

Dr Christopher Levi

13 September 2024

Date

Witness: Anne Williams

13 September 2024

Date