2024

HEALTH+MEDICAL RESEARCH

# Translational Research Grants Scheme Round 8

Full application

CLOSING DATE: 14 February 2025

NSW GOVERNMENT

## RESOURCES FOR APPLICANTS

Please note applicants are encouraged to refer to key TRGS resources to support the development of their Full Application, including:

- Your notification letter which includes individual feedback provided by the TRGS Expert Review Panel
- TRGS Guidelines for Applicants which includes an overview of selection criteria
- Appendix B, which includes detailed selection criteria and outlines key points to consider when addressing the selection criteria
- Translational Research Framework and Source Book

Other than the individual feedback, all educational resources are available at:
https://www.medicalresearch.nsw.gov.au/educational-resources/

## INSTRUCTIONS TO APPLICANTS

All Full Applications must be prepared using this form.

All sections of this form and attachments must conform to the following:

- Left and right margins of at least 2cm
- Font no smaller than 11 point (preferred font is Arial)
- Line spacing of 1.15

When saving this form, please use the naming convention: TRGS_FullApplication_<Host Organisation>_ <FirstnameSURNAME>
(e.g. TRGS_FullApplication_SWSLHD_JaneLEE).

Information provided in this Full Application will be provided to the Expert Review Panel and advisors supporting the Panel for the purpose of assessment.

## SUBMITTING THE FULL APPLICATION

The following documents are to be emailed to the TRGS Coordinator of the Host Organisation **by 5pm on Friday, 14 February 2025.**

- A Word version of the full application
- A PDF version of the full application
- Aboriginal Health Impact Statement
- Biographies
- 'Request for Partnering Organisation Approval' forms.

See the TRGS Coordinator List on the TRGS webpage for submission.

| SECTION A – ADMINISTRATIVE INFORMATION | |
|---|---|
| **TRGS Application number**<br>*Refer to the letter advising the outcome of the EOI stage* | DG24/7601 |
| **Host Organisation** | St Vincent's Health Network |
| **Name of TRGS Coordinator** | A/Prof Philip Cunningham OAM |
| **Email of TRGS Coordinator** | Philip.Cunningham@svha.org.au |
| **Administering Organisation Details**<br>*An Administering Organisation is a university, medical research institute, or not for profit organisation in NSW who manages the funds separate to the Host Organisation. Host Organisations may choose to partner with an Administering Organisation to hold the grant funds for the period of the grant. Further information around the eligibility of Administering Organisations can be found in the Guidelines.* | |
| **Will an Administering Organisation administer the funding?** | ☐ Yes<br>☒ No |
| **Name of Administering Organisation (if applicable)** | |
| **Administering Organisation Contact Name (if applicable)** | |
| **Administering Organisation Contact Email (if applicable)** | |
| **Chief Investigator(s) Details** | |
| **Chief Investigator's full name**<br>*Please include Title, First name and Surname*<br>*Should be consistent with the CI named in the EOI* | Prof Nadine Ezard |
| **Chief Investigator's email** | Nadine.ezard@svha.org.au |
| **Chief Investigator's contact number** | 0417651267 |

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| **Chief Investigator's organisation and address** | St Vincent's Health Network (SVHN)<br>390 Victoria St<br>Darlinghurst<br>NSW 2010 |
| **Chief Investigator's job title** | Clinical Director Alcohol and Drug Service |
| **Gender of Chief Investigator** | ☐ Male<br>☒ Female<br>☐ Non-binary<br>☐ Other _____ |
| **Chief Investigator's preferred pronouns (optional)** | |
| **Is the Chief Investigator a practising clinician?**<br>**If Yes:**<br>**a. In which area do you practise?**<br>**b. Will you continue clinical duties during this project?**<br>**c. If yes, what will be the FTE split between clinical and research duties?** | ☒ Yes<br>☐ No<br><br>☒ Medical<br>☐ Nursing<br>☐ Allied Health<br><br>☒ Yes<br>☐ No<br><br>0.4 FTE research duties<br>0.4 FTE clinical duties<br>0.2 FTE administrative duties |
| **Does the Chief Investigator identify as Aboriginal or Torres Strait Islander?** | ☐ Aboriginal<br>☐ Torres Strait Islander<br>☐ Aboriginal and Torres Strait Islander<br>☒ Neither |
| **Is there a Co-Chief Investigator for this project?** | ☒ Yes<br>☐ No |

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| **Co-Chief Investigator's full name (if applicable)**<br>*Please include Title, First name and Surname. Should be consistent with the Co-CI named in the EOI* | Dr Liam Acheson |
| **Co-Chief Investigator's email (if applicable)** | Liam.acheson@svha.org.au |
| **Co-Chief Investigator's contact number (if applicable)** | 0406544173 |
| **Co-Chief Investigator's organisation and address (if applicable)** | National Centre for Clinical Research on Emerging Drugs, c/o National Drug and Alcohol Research Centre, University of NSW (UNSW) |
| **Co-Chief Investigator's job title (if applicable)** | Postdoctoral Fellow |
| **Gender of Co-Chief Investigator (if applicable)** | ☒ Male<br>☐ Female<br>☐ Non-binary<br>☐ Other_____ |
| **Co-Chief Investigator's preferred pronouns (optional)** | |
| **Is the Co-Chief Investigator a practising clinician? (if applicable)**<br><br>**If Yes:**<br>**a. In which area do they practise?**<br><br>**b. Will they continue clinical duties during this project?**<br><br>**c. If yes, what will be the FTE split between clinical and research duties?** | ☐ Yes<br>☒ No<br><br>☐ Medical<br>☐ Nursing<br>☐ Allied Health<br><br>☐ Yes<br>☐ No<br><br>_____ FTE Research<br>_____ FTE Clinical Duties |
| **Does the Co-Chief Investigator identify as Aboriginal or Torres Strait Islander?** | ☐ Aboriginal<br>☐ Torres Strait Islander |

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| | ☐ Aboriginal and Torres Strait Islander<br>☒ Neither |
| **Project Details** | |
| **Project title**<br>*Please ensure the title describes the project clearly and avoids overly technical language* | Telehealth-delivered step-down for alcohol and other drug withdrawal |
| **Partnering Organisations and Research Sites**<br>*List the Partnering Organisation(s) [local health district, specialty health network, NSW Ambulance or NSW Pathology] and Research Site(s) where the project will be conducted* | Central Coast Local Health District (CCLHD)<br>Hunter New England Local Health District (HNELHD)<br>Nepean Blue Mountains Local Health District (NBMLHD)<br>Northern NSW Local Health District (NNSWLHD)<br>South Eastern Sydney Local Health District (SESLHD)<br>Sydney Local Health District (SLHD) |
| **Total funds requested (excluding GST)**<br>*Please specify funds in numerical form*<br>Note that the maximum grant request is $500,000. | $499,848 |
| **Submissions to other funding sources for this project**<br>*Include any planned or submitted applications. List the funder, expected date of notification of success and the amount(s) requested* | |
| **Does the project have an identified focus on Aboriginal health?**<br>Projects focused on **Aboriginal health** are those that:<br>• Are focused entirely on Aboriginal people, or<br>• Include a broader population but have a significant focus on Aboriginal people as a subgroup in the analysis. | ☐ Yes<br>☒ No |
| **If the project has an identified focus on Aboriginal health:**<br>**Is the project focused entirely on Aboriginal people?** | ☐ Yes<br>☒ No |

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| **Does the project include a broader population but have a significant focus on Aboriginal people as a subgroup in the analysis?** | ☐ Yes<br>☒ No |
| **Does the project have an identified focus on rural health?**<br>TRGS projects focused on **rural health** must satisfy both of the following:<br>1. The project is targeted to improving the health and wellbeing of people living in rural or remote areas, and<br>2. At least one Chief Investigator for the project is from an organisation based in a rural area and works in a rural or remote location.<br>For guidance on what is considered a rural or remote area, please refer to the Modified Monash Model.<br>Areas classified MM 3 to MM 7 are considered rural or remote for the purpose of the EOI stage. | ☒ Yes<br>☐ No<br><br>The project aims to support people to access safe and effective withdrawal support, especially relevant to those from rural areas |
| **If the project has an identified focus on rural health:**<br>**Is at least one Chief Investigator on the project from an organisation based in a rural area and works in a rural or remote location?** | ☒ Yes<br>☐ No |
| **If Yes:**<br>**Please provide the address where the CI is employed and working** | Professor Adrian Dunlop works at: Armidale Community Health, Moree Community Health, and Inverell Community Health.<br>Dr Patricia Collie works at: Lismore Base Hospital, Grafton, Ballina and Byron Bay |
| **Please specify the MM area for this address** (refer to the Modified Monash Model for the MM area) | ☒ MM3<br>☒ MM4<br>☐ MM5<br>☐ MM6 |

| | ☐ MM7 |
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| **Communication Summary**<br><br>Please provide a project summary including the following information to support us communicate your research to a wider audience:<br><br>**1. A research intent summary statement**<br>*Instruction: Provide a descriptive title that summarises the intent of the research project* ***(max 150 characters including spaces)***<br>**2. The issue for NSW**<br>*Instruction: Describe the issue the research will address* ***(120-150 words)***<br>**3. What does the research aim to do and how?**<br>*Instruction: Provide an overview of the research aim and methodology for the project* ***(75-100 words)***<br>**4. Top three (3) key measures/ indicators to assess research outcomes**<br>*Instruction: Provide the top (3) key measures/indicators being used to assess the research outcomes. These should be short and succinct key measures.*<br>**5. Project related images**<br>*Instruction: Please provide any project related images for inclusion with the project summary on* **https://www.medicalresearch.nsw.gov.au/**<br><br>*Please provide this information in Plain English. The language should be pitched at a high school age audience and avoid technical terminology. Please note that content provided may be used for media activity with content attributed to the lead researcher as a quote, should your application be successful.* | 1. To determine if a step-down model of withdrawal management can reduce hospital bed days without negatively impacting clinical outcomes when compared with usual care.<br>2. In NSW around 3 in 4 people use alcohol and 1 in 6 people use illicit drugs. In 2022-2023 approximately 45,000 people accessed treatment services for Alcohol and Other Drug (AOD) treatment in NSW, 14.1% of which were for withdrawal management. Inpatient withdrawal management provides highly supportive care to allow people to safely and successfully complete their withdrawal episode. However, current practice is inflexible and typically requires an inpatient admission of 5-7 days. This duration of hospitalisation is of significant burden, both at the individual level and health system level. Time in hospital for other conditions (e.g., childbirth) has shortened over recent decades, often facilitated by close outpatient follow up and telehealth services. However, this has not yet been translated to AOD services.<br>3. This research aims to determine if a step-down model of withdrawal management will reduce burden on healthcare systems without reducing patient safety. Patients who are admitted to a participating withdrawal management unit will undergo a structured risk assesment to ensure it is safe for them to participate. Eligible participants will then be invited to participate, and will receive either the step-down care, or treatment as usual.<br>4. The top measures of success in this project are |

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| | a. Reduced length of stay in hospital for those receiving the new model of care<br>b. No reduction in clinical outcomes (as defined by (a) completion of withdrawal episode; (b) engagement in ongoing alcohol and other drug care post discharge) or safety in those receiving the new model of care<br>c. The acceptability of the new model of care to patients and healthcare providers |

## SECTION B – RESPONSE TO FEEDBACK

**B.1 Please respond to feedback on the Expression of Interest provided by the Expert Review Panel (Maximum 500 words)**

The need and gap in practice seems obvious but it would help to enumerate and specify the extent of the need and the consequences of the gaps. The prima facie case for short stay assessment units is assumed but would also benefit from greater detail and specificity.

Thank you for noting this – the background sections of the proposal have been amended to better clarify the need for this model of care, and the case for pursuing this research.

Consider whether the main outcomes should be equality of withdrawal outcomes, as well as bed days.

No participant who agrees to participate in the trial will be discharged from the inpatient unit without clinical assessment for safety and suitability of enrolment in the step-down outpatient component of the trial. As such we will ensure clinical equivalence among the participants who receive step-down care versus those who receive standard care. However, the reviewer's suggestion of quantifying equality of withdrawal outcomes at treatment completion (discharge from withdrawal episode) between the two groups is an excellent one. We will be analysing the data using Bayesian methods which can quantify both difference *and* equivalence (via calculating probability density of a parameter that falls within a predefined Region Of Practical Equivalence (ROPE; see Kruschke 2014)). We can thus establish whether withdrawal outcomes are equal among the two groups of participants at treatment completion. We have added this outcome to the statistical analysis section of the application (Section E.1).

The control group would be those who declined step down care: the research team should consider that they may be systemically different; these should be either statistically controlled for, or else an alternative model used e.g. a cluster type randomisation.

The reviewer is right that our initial design would have led to a confound between the effects of the intervention and (systematic) individual differences between participants who chose either method. Their comment led to our rethinking the design of the study to remove this potential confound. We have decided instead to use a stepped-wedge design to measure differences in average length of stay. In stepped wedge designs each site has a control period – in our case when only standard care is offered to participants and an intervention period – when participants together with their clinical team can elect to engage in either standard care or step-down care. Thus each site acts as its own control. The period when the intervention period begins is staggered in waves across sites, with sites randomised to waves, see Figure 1. In this way whether a participant can choose step-down care or not – and hence whether they receive step-down care – is randomised, eliminating some of the confounding alluded to by the reviewer.

The primary analysis for the study will estimate difference in average length of stay during the pre-intervention and post-intervention periods. However, for some outcomes, we will still estimate differences between the participants who choose step-down care and those who choose standard care. As suggested by the reviewer, these analyses will include covariates primary drug of concern, age, gender, and socio-economic index for areas (SEIFA) rank by postcode of residence to control for potential between-subject differences (see section E.1)

More detail is required such as specific sample sizes for quantitative analyses.

We have revised the sample size calculations in Section E.1 in line with the new study design. While we are conducting many different types of analyses the calculations for the final study sample size can only be based on a single outcome: in our case that is the primary outcome, length of stay. Details are provided in Section E.1, but, briefly, we aim to recruit 336 participants to the study, 168 per condition (pre-intervention when step-down care is not offered vs post-intervention when step-down care is offered). This will be achieved by recruiting 1 per week at each of the six sites for 56 weeks, a rate which should be easily achievable given the known rates of admission and recruitment and the estimated difference in length of stay for the two models of care being compared. This sample size will give us 85% power to detect a true difference in the a priori estimated difference in length of stay between services that provide the intervention, and services which do not (details in Section E.1).

Could also benefit from stronger lived experience in investigator team

Thank you, the investigator team now includes Maureen Steele, who has a lived experience of substance use, in the investigator team. We have also consulted more widely with people who use drugs, and formalised the consumer advisory group in the governance structure of the grant. Please see stakeholders consulted and governance structure.

## SECTION C – PROJECT OVERVIEW - Maximum of two pages: additional pages for Project Overview will not be reviewed

Please resubmit your project overview from EOI stage and make updates where required.

| Key project details | Need for the research in NSW (Selection criteria: 1.1 – 1.5, 3.4) | Solution: Intervention/Approach (Selection criteria: 2a.2, 3.3) | Aim, research questions and hypotheses (Selection criteria: 2a.1) | Study design and methods (Selection criteria: 2a.2) | Outcome measures (Selection criteria: 2a.2 – 2a.3) |
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| **Chief investigator: Ezard and Acheson**<br><br>**Host organisation: SVHN**<br><br>**Project title: Telehealth-delivered step-down for alcohol and other drug withdrawal**<br><br>**Grant requested: $499,848**<br><br>**Research sites:**<br>**CCLHD**<br>**HNELHD**<br>**NBMLHD**<br>**NNSWLHD** | For childbirth and many forms of elective surgery, successive innovations have reduced time in hospital from as much as a week to as little as a day. However, for those admitted with alcohol or drug withdrawal, the length of hospital stay remains 5-7 days. Inpatient stays such as this may not reflect clinical need or often patient preference, and this inflexibility of services results in increased burden on the healthcare system<br><br>Across the seven Local Health Districts (LHDs) involved in this project approximately 5,350 admissions for substance withdrawal management are delivered every year. | We propose a stepped-care model of withdrawal management to address this gap.<br><br>Patients assessed for inpatient withdrawal management services will be fully assessed by the medical team at the participating LHD in line with the recently updated NSW Health 2022 *Management of Withdrawal from Alcohol and Other Drugs Clinical Guidance*.<br><br>Potentially eligible participants will be offered to enrol in the novel step-down model of care or continue their admission as usual.<br><br>Patients who receive the step-down service will be | The primary aim of this study is to determine the effectiveness of a step-down model of care for withdrawal management to reduce service utilisation of inpatient facilities by: Difference in inpatient average length of stay among eligible patients, between a service that offers step down care and one that does not, without negatively impacting clinical outcomes or safety.<br><br>Secondary aims include:<br>- Withdrawal safety<br>- Withdrawal severity<br>- Participant satisfaction<br>- Duration of withdrawal episode | Evaluation of the implementation of a service over a 12-month period, using a stepped wedge design, comparing average length of stay at a service which offers step-down withdrawal management and a service which only offers standard care withdrawal management.<br><br><u>Implementation Period</u><br>The new model of care will be implemented at each site at a randomly allocated timepoint, between 6 and 18 months from the start of the study. Participating LHDs will provide withdrawal management according to the step-down model of care from their allocated date of implementation. Service level outcome/process data will be extracted. Participants will be followed up via telephone 28 days following the completion of the withdrawal episode to assess health and substance use outcomes and engagement in post withdrawal services. A subset of participants | The primary outcome is reduced hospital utilisation, measured by the difference in mean length of stay of treatment episodes of participants receiving the stepped-care model of care compared to those receiving usual care.<br><br>Secondary outcome measures include safety (withdrawal complications documented by senior medical officers, emergency department representation within 48 hours), withdrawal severity, participant satisfaction; duration of withdrawal |

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| **SESLHD**<br>**SLHD**<br>**SVHN** | Of these, at least 1 in 3 (approximately 2000) admissions may not need such extended hospital stays, estimated on cross LHD consensus, provided appropriate ambulatory care is made available. However, there is currently no pathway for the transition of patients admitted to hospital to ambulatory care. We therefore propose a novel stepped-care approach to the management of withdrawal from alcohol and other drugs to facilitate this.<br><br>Structured risk-based pathways have been shown to reduce length of stay for alcohol withdrawal. A stepped-care model could reduce the duration of hospital admission by up to 5-days for eligible patients, reducing burden and unnecessary costs for the healthcare system and supporting patients to receive healthcare in an environment comfortable to them. | assessed daily for discharge from hospital (anticipated to be 1-3 days post admission) and transferred to telehealth delivered ambulatory care for the remainder of their withdrawal management by the service's existing community health team. This team will manage the participants withdrawal until the completion of the withdrawal episode.<br><br>During ambulatory withdrawal management each LHD will provide a combination of face-to-face and virtual (telehealth) care to ensure client safety and meet treatment outcomes.<br><br>Clinical management of patients will continue as per the 2022 guidelines including linkage into longer term treatment to prevent relapse. | - Withdrawal treatment completion<br>- Health service utilisation<br>- Substance use and health outcomes at 28 days<br>- Engagement in post-withdrawal care at 28 days<br>- Qualitative evaluation of facilitators and barriers of this model to patients and staff<br>- Reasons for ineligibility or refusal to participate<br>- Cost-consequence analysis<br><br>We hypothesise that implementing a step-down model of care for withdrawal management will reduce total number of bed days associated with withdrawal management without negatively impacting clinical outcomes or safety. | and clinicians will be interviewed to determine the acceptability of the model of care.<br><br>Data from our records indicate that 1 participant per week per site will be a realistic recruitment rate and that the average time in treatment with the current method is 5.0±1.9 days. Clinical experience suggests that (a) the average stay using the step-down method is approximately 2 days, (b) approximately 30% of eligible participants offered step-down care will take it. Thus, the estimated difference between average pre-Intervention length of stay and average post-Intervention length of stay = 5.0 – (5.0*(1-0.3) + 2*0.3) = 5 – 4.1 = 0.9 days, representing a medium standardised effect size of $d$ = 0.9/1.9 = 0.47. 1 participant recruited per week at each of 6 sites, for 56 weeks, equals 336 participants (168 in the pre-intervention period and 168 in the post-intervention period). Assuming a conservative intracluster correlation coefficient (ICC) of 0.04, the study will have 85% power to detect a difference in average length of stay between the pre- and post-intervention period of 0.9 days. | episode (combining inpatient and outpatient); treatment completion, health services utilisation; health and substance use (Australian Treatment Outcomes Profile) type and number of post-withdrawal services accessed; qualitative interviews with staff and participants; the overall cost, cost per treatment episode and change in average bed days pre and post implementation; proportion of service users eligible for the model, and proportion of those eligible who participate in the new model. |

## SECTION D – EVIDENCE BASE, RESEARCH QUESTION AND INTERVENTION

This section should be no longer than 2 pages.

**D.1 Describe the problem being addressed by the proposal and the evidence gap being addressed. Explain how the problem was identified. (Selection criteria: 1.1, 1.3)**

Inpatient withdrawal management provides highly supportive care to allow people to safely and successfully complete their withdrawal episode. However, current practice is inflexible and typically requires an inpatient admission of 5-7 days. This duration of hospitalisation is of significant burden, both at the individual level and health system level. Time in hospital for other conditions (e.g., childbirth) has shortened over recent decades, often facilitated by close outpatient follow up and telehealth services (1). However, this has not yet been translated to AOD services. Expert consensus from the Clinical Directors of the seven LHDs, following a recent revision of the *NSW Health Management of Withdrawal from Alcohol and Other Drugs Clinical Guidance (2),* involved in this project has identified a potential solution – providing the option of a step-down model of care for patients admitted to hospital for alcohol and/or drug withdrawal. Based on clinical risk assessment, this would allow for patients to complete withdrawal in the community, reducing burden on hospital beds and allowing people to receive care from the comfort of their own homes with access to personal supports.

**D.2 Explain why the problem is of significance in NSW and why it matters to NSW Health. (Selection criteria: 1.2)**

In NSW approximately 3 in 4 people consume alcohol and 1 in 6 people use illicit drugs (3). In 2022-2023 approximately 45,000 people accessed specialist treatment services for AOD treatment in NSW, 14.1% of which were for withdrawal management (4). The proposed model of care is therefore of significance to NSW for two main reasons; in the post-COVID economic environment this proposal has the potential to reduce bed days, saving money across multiple health districts, and; improve access to withdrawal management and allow people more autonomy, flexibility and choice in how they receive their withdrawal management. This proposal has the potential to improve health services for vulnerable people, while also having economic implications for the sector. As this proposal leverages existing infrastructure it will be rapidly implementable and scalable across the State.

**D.3 Describe the aims of the research, including a clear statement of the research questions and hypotheses. (Selection criteria: 2a.1)**

The primary aim of this study is to determine the effectiveness of a step-down model of care for withdrawal management to reduce service utilisation of inpatient facilities, without negatively impacting clinical outcomes or safety. The secondary aims of this study are to demonstrate the difference pre- and post-implementation of the new model on measures of: withdrawal safety; withdrawal symptom severity; completion of withdrawal episode; participant satisfaction; number of hospital and community episodes of care; substance use and health outcomes at 28 days; engagement in post-withdrawal care at 28 days; qualitative evaluation of facilitators and barriers of this model to participants and staff; reasons for ineligibility or refusal to participate and; cost-consequence analysis

The primary research question is: What is the difference in average length of stay, among eligible participants, between a service that offers step-down care and one that does not? We hypothesise that implementing a step-down model of care for withdrawal management will reduce the total number of bed days associated with withdrawal management without negatively impacting clinical outcomes or safety.

**D.4 Provide a clear description of the intervention, and why this will address the problem described in D.1. (Selection criteria: 1.4, 2a.2)**

We propose a step-down model of care for withdrawal management, aligning with other healthcare services and sectors towards a more flexible, patient-oriented treatment experience. This model of care will be developed by clinicians, peer workers and advocates, and Aboriginal Health workers across all districts involved in this application.

Patients presenting for inpatient withdrawal management will be fully assessed by the medical team and a treatment plan developed at the LHD in line with the recently updated NSW Health 2022 *Management of Withdrawal from Alcohol and Other Drugs Clinical Guidance*. Eligible participants include people dependent on alcohol and /or other drugs, and for whom inpatient admission is indicated in accordance with the *Clinical Guidance* (e.g. concurrent illness; moderate or severe withdrawal is predicted; history of serious withdrawal complications; likely withdrawal from other substances). Potentially eligible participants will be offered participation in the novel step-down model of care or offered the treatment as usual inpatient withdrawal. Patients who receive the step-down service will be assessed daily for suitability for discharge from hospital for community-based withdrawal completion, expected to be 1-3 days post admission, and transferred to telehealth delivered ambulatory care for the remainder of their withdrawal management by the service's existing community health team. This team will manage the participant's withdrawal until the completion of the withdrawal episode. The full model of care and risk assessment framework are to be developed during the first 6 months of this project with people with a lived/living experience of drug use from all districts involved in the design and implementation of the model.

During the community-based withdrawal management component of the intervention, each LHD will provide a combination of face-to-face and virtual (telehealth) care to ensure clinical safety, and to meet treatment outcomes (based on local service availability). Clinical management of patients will continue as per the 2022 *Clinical Guidance* including daily reviews and staged supply of medication during the acute withdrawal period (anticipated 3-7 days in total) and linkage into continuing care.

This intervention will allow patients to continue to receive support (e.g. from family or friends) in their familiar home environment whilst receiving withdrawal care. Doing this in the context of medical and nursing oversight ensures that any clinical deterioration or complications associated with withdrawal are identified and managed promptly. Further, the model of care allows for inpatient beds to be reserved for the most severe presentations, and for emergency presentations for withdrawal that require 24/7 nursing care.

**D.5 Provide evidence of whether the proposed intervention/activity has been evaluated or tested/validated before. Describe any preliminary findings/pilot data and how they will be built on through the proposed intervention. (Selection criteria: 1.4 – 1.5)**

There is very strong evidence that reduced length of stay generally improves health outcomes as well as economic outcomes. For example, reduced length of stay post childbirth is associated with lower cost, lower rates of infection and improved satisfaction (1, 5). Following general elective surgeries, programs which reduce length of stay are also associated with lower complications and either no change in, or a reduction in readmission rates (6). Existing randomised controlled trials (RCTs) comparing inpatient versus ambulatory management of withdrawal show generally similar outcomes (7). Whilst this has not been attempted in inpatient withdrawal management for AOD services, ambulatory withdrawal has been demonstrated to be acceptable to patients (8, 9). Combining an initial admission with a step-down to telehealth delivered care has the potential to provide effective, safe and acceptable ambulatory care to patients who normally would only be offered a hospital admission. The cost-savings, as well as the potential to improve satisfaction with care received is worth the risk of attempting the research. Learnings from decades of attempts to reduce length of stay in other settings, as well as modern withdrawal management guidelines, will inform the proposed model of care.

## SECTION E – RESEARCH DESIGN, METHODS AND OUTCOME MEASURES

This section should be no longer than 6 pages

### E.1 Provide a detailed description of the research design, methods and outcome measures. (Selection criteria: 2a.2)

**Research Design**

This study will evaluate the implementation of a new step-down model of care for withdrawal from alcohol and other drugs over a 12-month (56-week) period using a stepped-wedge study design. The goal is to determine the difference in average length of stay, among eligible participants, between the pre-intervention and post-intervention period.

**Methods**

The new model of care will be implemented 6 months from the start of the study, to allow time for the new model of care to be developed. We will employ a stepped-wedge study design, where each of the six participating services will be randomly allocated to begin the intervention at different times. The experimental period will consist of a 56-week duration, with six 8-week waves, one wave per site. Sites will be randomly allocated to waves, meaning the start date of the intervention is random for each site. This is outlined in Figure 1. During the pre-intervention period all participants will receive standard care withdrawal management. During the intervention period eligible participants, in consultation with their site clinical team, will elect to engage in either withdrawal management according to the step-down model of care, or inpatient withdrawal management as per standard of care.

| | Weeks 1-8 | Weeks 9-16 | Week 17-24 | Weeks 25-32 | Weeks 33-40 | Weeks 41-48 | Weeks 49-56 |
|---|---|---|---|---|---|---|---|
| Site 1 | | | | | | | |
| Site 2 | | | | | | | |
| Site 3 | | | | | | | |
| Site 4 | | | | | | | |
| Site 5 | | | | | | | |
| Site 6 | | | | | | | |

Figure 1: Site allocation for stepped-wedge trial design. Blue = pre-intervention period, white = intervention period

**Eligibility**

Participants will be eligible to participate in this study if they have been admitted to a participating withdrawal management unit, are 18 years of age or over, are willing to be followed up post withdrawal episode and willing to provide written informed consent. Participants will be excluded if they are at high risk of medical complication, have significant coexisting physical or mental conditions or social complexities that necessitate prolonged hospitalisation, or if they are assessed as eligible for ambulatory withdrawal.

**Procedure**

On admission to a withdrawal unit all participants will undergo eligibility screening. Those who are eligible to participate will be invited to participate. During the pre-intervention period participants will only be eligible to receive usual care (inpatient) withdrawal management. During the intervention period participants will be asked to self-nominate to receive either the stepped-care model or standard of care. Those who opt in to receive the new model of care will be assessed daily for transfer to community-based telehealth withdrawal management services (anticipated between Days 1-3) to complete the withdrawal episode, and will receive telehealth delivered withdrawal management up until the end of their withdrawal episode. Figure 2 outlines the procedure during the intervention phase.

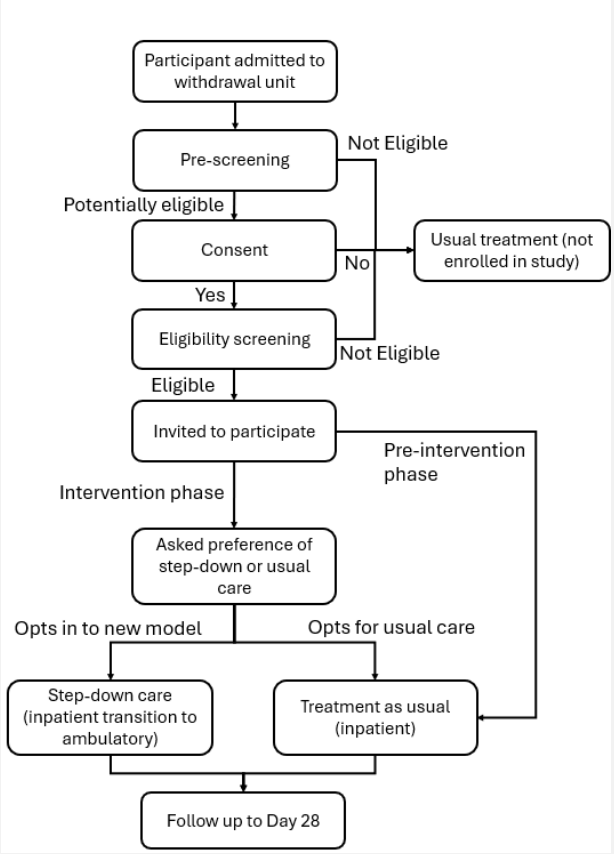


Figure 2. Study flow diagram

Participants who receive usual care (either those enrolled before the intervention period or those who opt not to step-down in the intervention period) will receive standard of care inpatient withdrawal management as per the *NSW Health Management of Withdrawal from Alcohol and Other Drugs Clinical Guidance*, including daily medical and nursing reviews, management of co-existing disorders, and provision of medication and psychosocial care as per standard. Participants who receive step-down care will receive standard care inpatient withdrawal management until their discharge to community-based telehealth services to finish their withdrawal episode. During the outpatient period participants will receive daily assessment from a doctor or nurse as per local site practices and may be prescribed medication if clinically indicated. The final day of the withdrawal episode will be determined on an individual basis based on clinical presentation and individual needs. On the final day of the withdrawal episode each participant will complete a paper-based or electronic participant satisfaction questionnaire, a subjective withdrawal severity measure, as well as a modified Timeline Followback to assess substance use. The participant will then be discharged from the study.

Service level outcome/process data will be extracted from routine data to determine total length of stay in each service, withdrawal episode completion and safety.

Participants will be followed up via telephone at Day 28. The telephone interviews will assess health and substance use outcomes (using the Australian Treatment Outcomes Profile) and engagement in post withdrawal services.

A subset of 20 client participants (10 who received the step-down model of care and 10 who received usual care) and 10 clinicians involved in the provision of the new model of care will be interviewed to determine the acceptability of the model of care. For client participants, interviews will be conducted between the end of their withdrawal episode and their Day 28 follow up at a time convenient to them (within a 3-day window). Clinician participants will be interviewed throughout the lifetime of the implementation period, to ensure that perspectives cover as broad a timeframe as possible. All interviews will be conducted by a Project Coordinator with training in qualitative interview techniques, via Zoom, Microsoft Teams or other videoconferencing software.

**Outcome measures**

The primary outcome is average per-patient hospital utilisation, measured by the difference in mean inpatient length of stay of treatment during the pre-intervention period (when participants can only receive usual care) compared with the post-intervention period (when participants can choose either standard care or step-down care)

Secondary outcomes and their associated measures are presented in the table below:

| Secondary Outcome | Outcome Measure | Primary predictor(s) |
|---|---|---|
| Withdrawal safety | Routinely collected clinical data including adverse events, mortality, ED representation within 48 hours of discharge from inpatient unit | Care Type (standard vs Step-Down)<br><br>Study Period (Pre-Intervention vs Post-Intervention) |
| Participant satisfaction | Satisfaction questionnaire | Care Type (standard vs Step-Down)<br><br>Study Period (Pre-Intervention vs Post-Intervention) |
| Withdrawal symptom severity | Subjective withdrawal severity scale | Care Type (standard vs Step-Down) |
| Duration of withdrawal episode of care | Duration of withdrawal treatment episode of care (combining inpatient and outpatient) | Care Type (Standard vs Step-Down) |
| Completion of withdrawal treatment | Withdrawal treatment completion<br>Modified Timeline Follow Back | Care Type (Standard vs Step-Down) |
| Health service utilisation | Number of hospital and community episodes of care | Study Period (Pre-Intervention vs Post-Intervention) |
| Substance use and health outcomes at 28 days | Australian Treatment Outcomes Profile | Care Type (Standard vs Step-Down) |
| Engagement in post-withdrawal care at 28 days | Type and number of post-withdrawal services accessed | Care Type (Standard vs Step-Down) |
| Qualitative evaluation of facilitators and barriers of this model to patients and staff | Qualitative interviews | Not applicable |
| Reasons for ineligibility or refusal to participate | Routinely collected clinical and research data<br><br>Qualitative interviews | Not applicable |
| Cost-consequence | The overall cost, cost per treatment episode and change in average bed days<br><br>Proportion of service users eligible for the model, and proportion of those eligible who participate in the new model | Care Type (standard vs Step-Down)<br><br>Study Period (Pre-Intervention vs Post-Intervention) |

**Statistics**

*Power Calculation*

Data from our records indicate that 1 participant per week per site will be a realistic recruitment rate for the study and that the average time in treatment with the current method is 5.0±1.9 days. Clinical experience suggests that (a) the average stay using the step-down method is approximately 2 days, (b) approximately 30% of eligible participants offered step-down care will take it. Thus the estimated difference between average Pre-intervention length of stay and average Post-intervention length of stay = 5.0 – (5.0*(1-0.3) + 2*0.3) = 5 – 4.1 = 0.9 days, representing a medium standardised effect size of $d$ = 0.9/1.9 = 0.47 (10). 1 participant recruited per week at each of 6 sites, for 56 weeks, equals 336 participants (168 in the pre-intervention period and 168 in the post-intervention period). Assuming a conservative intracluster correlation coefficient (ICC) of 0.04, the study will have 85% power to detect a difference in average length of stay between the pre- and post-intervention period of 0.9 days.

*Analysis*

All analyses will be conducted using Bayesian parameter estimation, which estimates proportion of probability density falling within a predefined interval and hence allows for estimates of equality as well as difference. The primary outcome, length of stay (one observation per participant), will be analysed with a Level-1, hierarchical repeated measures regression model, with fixed factors Study Period (binary within-site categorical variable, pre-intervention vs post-intervention) and primary drug of concern, age, gender, postcode of residence SEIFA rank, (covariates) and random factor site (six-level categorical variable indicating Site ID). Other single-observation outcomes (e.g. completion of withdrawal treatment) will be analysed with single-level (i.e. non-hierarchical) regression with predictors care type (binary between-subject categorical predictor: standard care vs step-down care) and covariates principle drug of concern, age, gender, and SEIFA rank Some single-observation outcomes will be analysed using both the hierarchical and single-level models described above.

Numeric outcomes (e.g. the primary outcome, length of stay, withdrawal score) will be analysed using standard Gaussian regression, binary categorical outcomes (e.g. withdrawal episode completion) with Bernoulli regression, bounded count outcomes (i.e. where count has upper limit e.g. days of substance use at follow up) with binomial regression, and unbounded counts (i.e. where count has no known limit, e.g. adverse events) with Poisson or negative binomial regression. Time to event data (e.g. mortality) will be analysed with Cox Proportional Hazards regression.

Qualitative interviews will be transcribed and coded using a conventional content analysis approach (11). Data will be analysed according to a Theoretical Framework of Acceptability, which consists of seven component structures which influence how a person accepts healthcare interventions (12).

**E.2 Provide details about any costing component or economic evaluation. (Selection criteria: 2a.2, 3.7)**

This study includes a formal health economics evaluation, budgeted as an implementation scientist to evaluate the economic impacts of the program. Health economic evaluation will include the overall cost of the model, cost-per-treatment episode and change in average bed days between groups. Economic models will include proportion of service users eligible for the model, and proportion of those eligible who choose to participate.

### E.3 Indicate where, on the Translational Research Continuum, current evidence exists and where this proposal sits

Refer to the Translational Research Framework. NB: 'Idea generation' and 'Monitoring' is out of scope for TRGS.

| | Feasibility | Efficacy | Replicability and adaptability | Effectiveness | Scalability |
|---|---|---|---|---|---|
| **Current evidence** | x | | | | |
| **Proposed research** | x | x | | | |

### E.4 Describe why you consider the current evidence to be at the indicated stage of translation.

While there is strong evidence for the feasibility, efficacy and scalability for step-down models of care in other fields of medicine to reduce hospital burden, there is limited evidence for its use in withdrawal management. Despite this, ambulatory and telehealth delivered withdrawal services are acceptable to patients, and AOD services have expanded their telehealth services during the COVID pandemic. It is feasible to leverage these existing services to a step-down model of care.

### E.5 Describe how and why the knowledge will progress to the indicated stage of translation, as a result of your project

Data generated by this project will provide initial efficacy evidence for the proposed model of care for reducing bed days (primary) and completing withdrawal episodes (secondary) without impacting on participant safety or withdrawal severity. The acceptability and feasibility of the model will further be assessed with qualitative and quantitative investigation of participant and provider perspectives, and the consumer advisory group will support the translation of the project in a manner acceptable to community. By including a diverse range of metropolitan and rural LHDs in this protocol the adaptability and utility of this model across NSW can also be evaluated.

## SECTION F – RESEARCH IMPACT

This section should be no longer than 1 page.

**F.1 Describe how the research proposal will achieve impact against *one or more* of the strategic outcomes outlined in the Future Health Strategic Framework 2022-2032. (Selection criteria: 1.6, 3.3)**

*Note some outcomes may be more relevant to each project than others but we encourage you to consider the impact of the research against the six strategic outcomes.*

This project will achieve impact against outcomes 2.1, 2.2 and 6.1 of the Future Health Strategic Framework 2022-2023. The proposed model of care will allow for high-quality withdrawal management to be offered to people in ambulatory settings who otherwise would have to remain hospitalised. This will improve patient-centred care by allowing people to receive care in line with current guidelines at their homes, facilitating work and caring responsibilities for those who need it. Further, this model will allow pivot to services delivered in the home or community rather than the hospital, meeting the outcomes *2.1 Deliver safe, high quality reliable care for patients in hospital and other settings* and *2.2 Deliver more services in the home, community and virtual settings*

By providing capacity to step-down patients from hospital to community based healthcare this proposal has the potential to reduce bed days, and therefore overall cost to the health system. Importantly however, as described in the literature people who complete withdrawal management in the community often have better treatment outcomes than those who complete as inpatient, and this proposal will allow us to ensure value-based healthcare which has the potential to meet or exceed current treatment outcomes. This will meet outcome *6.1 Drive value based healthcare that prioritises outcomes and collaboration.*

This proposal also has the potential to meet the other outcomes in the framework by improving participant experiences and outcomes with more flexible healthcare delivery (Outcome 1), improving the health and welfare of vulnerable people (Outcome 3), engaged and connected staff fostering better collaboration between inpatient, hospital in the home and assertive community management services (Outcome 4) and driving research and innovation through multiple health districts (Outcome 5).

**F.2 Describe how your chosen outcome measures will evaluate impact against *one or more* of the strategic outcomes in the Future Health Strategic Framework 2022-2032. (Selection criteria: 2a.3)**

Our primary outcome measure of change in bed days is well suited to evaluate impact towards both service utilisation and economic outcomes, in line with Outcomes 2 and 6 of the Strategic Framework. Secondary outcomes of number of treatment episodes and duration of care will be used to measure impact against Outcomes 2 and 6. Service level clinical data and the Australian Treatment Outcomes Profile will allow evaluation of the safety of the intervention and detection of change in clinical outcomes, addressing Outcomes 2 and 3. Qualitative interviews with staff and patients will be used to evaluate the acceptability and utility of the model of care from the perspectives of both the staff who deliver the care as well as the patients who receive it, and will address outcomes 1 and 4. Finally the cost-consequences outcomes and feasibility of the model will evaluate the impact of the service against Outcome 6.

## SECTION G – REFERENCES AND PUBLICATIONS

**G.1 Include a list of references used to describe the Research Proposal outlined in C-F.**

1. Askelsdottir B, Lam-de Jonge W, Edman G, Wiklund I. Home care after early discharge: impact on healthy mothers and newborns. Midwifery. 2013;29(8):927-34.
2. NSW Ministry of Health. Management of withdrawal from alcohol and other drugs: Clinical guidance. Sydney, Australia; 2022.
3. AIHW. National Drug Strategy Household Survey 2022–2023. AIHW Canberra; 2024.
4. AIHW. Alcohol and other drug treatment services in Australia annual report. Canberra: AIHW; 2024.
5. Stas A, Breugelmans M, Geerinck L, Spinnoy A, Van Laere S, Gucciardo L, et al. Maternal satisfaction with reduced postnatal length of stay in Brussels: evidence from the KOZI&Home program. BMC Pregnancy and Childbirth. 2023;23(1):475.
6. Ban KA, Berian JR, Ko CY. Does implementation of enhanced recovery after surgery (ERAS) protocols in colorectal surgery improve patient outcomes? Clinics in colon and rectal surgery. 2019;32(02):109-13.
7. Lee J, Hulman S, Musci Jr M, Stang E. Neonatal abstinence syndrome: influence of a combined inpatient/outpatient methadone treatment regimen on the average length of stay of a Medicaid NICU population. Population Health Management. 2015;18(5):392-7.
8. Rens E, Ceelen A, Martens N, Van Camp L, Destoop M. Home-based detoxification for individuals with alcohol or drug dependence: A systematic review of the recent literature. Drug and Alcohol Review. 2024.
9. Mussared J, Oni HT, Gregory TJ, Fernandes A, Mazzacano A, Kadarusman D, et al. An In-Home Withdrawal Service for individuals with low-to-moderate substance dependence: implementation and program evaluation. Australian Journal of Primary Health. 2024;30(4).
10. Cohen J. Statistical power analysis for the behavioral sciences: routledge; 2013.
11. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. Qualitative health research. 2005;15(9):1277-88.
12. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC health services research. 2017;17:1-13.

**G.2 If the investigators have published or presented any preliminary or relevant research to the proposed project please include these here. (Selection criteria: 2b.1; 1.4)**

1. **Lintzeris N**, Sunjic S, Demirkol A, Branezac M, **Ezard N**, **Siefried K… Acheson LS… Haber P**. Management of withdrawal from alcohol and other drugs: an Evidence Check rapid review brokered by the Sax Institute (www.saxinstitute.org.au) for the NSW Ministry of Health. 2019.
2. NSW Ministry of Health. Management of withdrawal from alcohol and other drugs: Clinical guidance. Sydney, Australia; 2022. (*Investigators Haber P, Lintzeris N, Ezard N, and Acheson L contributed to this guidance*)
3. **Siefried KJ, Acheson LS, Lintzeris N, Ezard N**. Pharmacological Treatment of Methamphetamine/Amphetamine Dependence: A Systematic Review. CNS Drugs. 2020.
4. **Acheson LS**, Williams BH, Farrell M, McKetin R, **Ezard N, Siefried KJ**. Pharmacological treatment for methamphetamine withdrawal: A systematic review and meta-analysis of randomised controlled trials. Drug and Alcohol Review. 2023;42(1):7-19.
5. **Acheson LS, Ezard N, Lintzeris N, Dunlop A**, Brett J, Rodgers C… **Siefried KJ**. Lisdexamfetamine for the treatment of acute methamphetamine withdrawal: A pilot feasibility and safety trial. Drug and alcohol dependence. 2022:109692.
6. **Siefried KJ**, Freeman G, Roberts DM, Lindsey R, Rodgers C, **Ezard N**, et al. Inpatient GHB withdrawal management in an inner-city hospital in Sydney, Australia: a retrospective medical record review. Psychopharmacology. 2023;240(1):127-35.
7. **Haber PS, Lintzeris N**. Alcohol Withdrawal. Alcohol Withdrawal: Specialty of Addiction Medicine, Faculty of Medicine and Health, The University of Sydney; 2021. p. 101-39.
8. Oakley B, Wilson H, Hayes V, **Lintzeris N**. Managing opioid withdrawal precipitated by buprenorphine with buprenorphine. Drug and Alcohol Review. 2021;40(4):567-71.
9. Allsop DJ, Copeland J, **Lintzeris N, Dunlop AJ**, Montebello M, Sadler C, et al. Nabiximols as an Agonist Replacement Therapy During Cannabis Withdrawal: A Randomized Clinical Trial. JAMA Psychiatry. 2014;71(3):281-91.

## SECTION H – ABORIGINAL HEALTH IMPACT STATEMENT

**H.1 Complete an Aboriginal Health Impact Statement and explain how the statement will be addressed in the study below (Selection Criteria: 1.7)**
*Maximum 300 words.*

To ensure the Aboriginal Impact Statement is addressed by the study, this proposal was developed with Aboriginal Health Workers at the lead site. To ensure cultural input to the project, Aboriginal Health Workers from each of the LHDs involved will be invited to participate in the development of the model of care. This has been budgeted as in-kind support from each site. The research team had partnered with Dr Cilla Zhou, research partnerships manager at study partner the National Centre for Clinical Research on Emerging Drugs (NCCRED), who will use their experience in managing community input in research to ensure meaningful collaboration and communication.

This proposal has budgeted for a part-time Aboriginal Researcher to assist in the project. By budgeting for this role, this proposal will support the training and education of the next generation of Aboriginal Researcher. This role will be supervised by the investigator team, and will assist in the interpretation of the study findings to allow for culturally informed results and dissemination. Ensuring the Aboriginal Impact statement is addressed is the responsibility of CIs Ezard and Acheson, who will oversee the project.

Complete an Aboriginal Health Impact Statement. The template for the Aboriginal Health Impact Statement can be found in Attachment 1 in this policy directive:
https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2017_034.pdf
Provide your full completed Aboriginal Health Impact Statement as an attachment to this application.

## SECTION I – TEAM AND TIMEFRAME

### I.1 Chief Investigator details

The Chief Investigator (applicant) must be employed by the Host Organisation. Note that the Chief Investigator should be consistent with the Expression of Interest.

| | |
|---|---|
| Full Name:<br>*Please include title* | Prof Nadine Ezard |
| Position: | Clinical Director, Alcohol and Drug Service |
| Organisation: | SVHN |
| Full Name:<br>*Please include title* | Dr Liam Acheson |
| Position: | Postdoctoral Fellow |
| Organisation: | UNSW, SVHN |

### I. 2 Chief Investigator (Selection Criteria: 2b.1, 2c.2)

Outline the Chief Investigator's role in the research and describe why the Chief Investigator's involvement is critical to the success of the research. *Maximum 250 words.*

Prof Ezard's role in this project is to act as Coordinating Principal Investigator on this study, leading the development of the model of care, overseeing the overall conduct of the study, and leading dissemination and translation. They are site principal investigator at SVHN, where they will be responsible for the implementation of the model of care, training of staff to deliver the new model of care and the recruitment of participants.

Prof Ezard is the Clinical Director of the Alcohol and Drug Service (ADS) at SVHN and the Director of NCCRED. They have decades of experience in the management and treatment of substance use disorders, in inpatient and outpatient settings, and providing AOD care via telehealth. Prof Ezard is an experienced clinical researcher with a proven track-record of coordinating multi-site clinical research projects and trials across Australia.

Dr Acheson's role will be to lead the development of the research protocol and assist with the development of the model of care, under the supervision of Prof Ezard. They will coordinate the data analysis and lead the dissemination activities, including developing media to translate the results. They are responsible for convening the consumer advisory groups and ensuring community input in the project.

Dr Acheson is a postdoctoral research fellow with NCCRED and SVHN ADS. They have experience conducting clinical research projects, including clinical trials and qualitative studies within inpatient withdrawal management units. Dr Acheson will leverage this experience of conducting research in inpatient settings to ensure the success of the project.

### I. 3 Associate Investigator(s) (Selection Criteria: 2b.1, 2c.2)

Specify the proposed investigators in the below table (maximum 10).

| # | Full Name | Position | Organisation | Contribution to the project |
|---|---|---|---|---|
| 1 | Prof Nick Lintzeris | Associate Investigator | SESLHD | Project conception, study design, coordination of a study site |
| 2 | Prof Adrian Dunlop | Associate Investigator | HNELHD | Project conception, study design, coordination of a study site |
| 3 | Prof Paul Haber | Associate Investigator | SLHD | Project conception, study design, coordination of a study site |
| 4 | Dr Patricia Collie | Associate Investigator | NNSWLHD | Project conception, study design, coordination of a study site |
| 5 | Dr Karen Fisher | Associate Investigator | NBMLHD | Project conception, study design, coordination of a study site |
| 6 | Dr Llew Mills | Associate Investigator | University of Sydney | Statistical support, study design, analysis |
| 7 | Dr Krista Siefried | Associate Investigator | SVHN / NCCRED / UNSW | Study design, analysis, dissemination |
| 8 | Dr Brendan Clifford | Associate Investigator | SVHN / NCCRED / UNSW | Study design, analysis, dissemination |
| 9 | Maureen Steele | Associate Investigator | NSW Ministry of Health | Peer representative. Study design, interpretation of findings, dissemination |
| 10 | Steven Childs | Associate Investigator | CCLHD | Development of the model of care and translation of results to regional treatment settings |

### I.4 Biographies (Selection criteria: 2b.1, 2c.2)

Please provide an attachment that includes a brief biography for each member of the research team (maximum one page per investigator). Investigators with policy or practice experience on the research team will be considered for the explicit value that expertise brings. Achievements relevant to the research proposal should be included in the biography.

Please save the biographies **as a single file** using the following naming convention:
TRGS_Full Application_<Organisation>_<Chief Investigator name>_Biographies
(e.g. TRGS_Full Application_NNSWLHD_DavidSMITH_Biographies)

### I.5 PhD student (if applicable)

Please fill in the below table if a PhD student will be included in the research team and contribute to the TRGS project. See page X of the Applicant Guidelines for further information.

| Academic Supervisor | Host University | Length of PhD in years | Expected start and completion date | Role of the PhD student (i.e. contribution to the TRGS project) | Deliverables of the PhD student | Description of supervision and research arrangements during the TRGS project and beyond |
|---|---|---|---|---|---|---|
| | | | | | | |

### I.6 Research and Translation/ Implementation Partners (Selection criteria 2b.2, 3.2)

Specify essential partners required for successful conduct of the project and translation/implementation of the outcomes in the below table. Partners are unlimited.

For each identified partner, outline their contribution to the project including when and how they will be engaged in the research (e.g. in defining the problem, designing and/or delivering the intervention) and translation activities (e.g. dissemination of research outputs or findings, implementation of findings in policy or practice). *Note that all partners listed should be confirmed at the time of submitting this Full Application*.

Applicants are encouraged to partner with other Host Organisations to assist with generalisability of the research findings. If this is not considered appropriate for the research project, please provide justification.

| # | Full Name | Position | Organisation | Contribution to the project |
|---|---|---|---|---|
| 1 | Michelle Hall | Coordinator | DACRIN | Assistance with the conduct of the study and dissemination of findings |
| 2 | Dora Karavasilis | Knowledge Translation Lead | NCCRED | Novel dissemination of |

| | | | | |
|---|---|---|---|---|
| | | | | research outputs through animated media |
| 3 | Steven Childs | Manager | Drug and Alcohol Services, CCLHD | Development of the model of care and translation of results to regional treatment settings |

**I.7 Other Stakeholders Consulted (Selection criteria: 1.3, 1.5, 3.3 - 3.5)**
Specify stakeholders who have been consulted in the development of the proposal and those who will be consulted when implementing the research findings. Consulted stakeholders are unlimited.

| # | Full Name | Position | Organisation | Contribution to the project |
|---|---|---|---|---|
| 1 | Meg Williamson | Telehealth and Innovation Manager | SVHN | Expertise in telehealth delivery of AOD care |
| 2 | Zalehah Turner | Peer Worker | SVHN | Critical review of project. Will guide the development of the model of care, research processes and evaluation to ensure it meets the needs of community |
| 3 | Adrian Tait | Peer Worker | SVHN | Critical review of project. Will guide the development of the model of care, research processes and evaluation to ensure it meets the needs of community |
| 4 | Charli Lay | Peer Worker | SVHN | Critical review of project. Will guide the development of the model of care, research processes and evaluation to ensure it meets the |

| | | | | |
|---|---|---|---|---|
| | | | | needs of community |
| 5 | Kat Fry | Inner City Health Program Peer Coordinator | SVHN | Critical review of project. Will support peer workers and ensure community representation |
| 6 | Wendy Williams | Aboriginal Health Worker | SVHN | Review of project to ensure cultural relevance and safety. Will assist in the design of the model of care to ensure that it meets the needs of Aboriginal and Torres Strait Islander patients |
| 7 | Michael Carriage | Aboriginal Health Worker | SVHN | Review of project to ensure cultural relevance and safety. Will assist in the design of the model of care to ensure that it meets the needs of Aboriginal and Torres Strait Islander patients |
| 8 | Cilla Zhou | Research Partnerships Manager | NCCRED | Will ensure meaningful partnerships with community and assist in the organisation and running of community advisory groups |

**I.8 Governance Structure (Selection criteria: 2b.3)**

Based on I.3 and I.6, list the members of the project Steering Committee and other governance structures such as Advisory Groups and Working Groups that are relevant to the project.

The overall project governance will be managed by a protocol steering committee, co-chaired by Prof Ezard and Dr Acheson who will be responsible for initial drafting of the protocol and all subsequent amendments. These will go to the project steering committee for comment and ratification.

The project steering committee will be co-chaired by Prof Ezard and Dr Acheson, and will include all named CIs and AIs. All major decisions will go to this group.

A model of care working group inclusive of all site clinical directors/managers (Ezard, Lintzeris, Dunlop, Haber, Collie, Fischer, Childs) will be responsible for developing the new model of care prior to its implementation.

A Consumer Advisory Group (CAG) will be convened to ensure community oversight of the project. Peer workers from each LHD involved, as well as other members of the community will be invited to participate. The CAG will feedback to the relevant committees on the protocol, model of care and the interpretation and dissemination of results.

Note that CCLHD is participating as a research partner (participating in the development of the model of care, analysis of the findings, and subsequent post-trial implementation planning) but not a recruitment site.

### I.9 Project milestones (Selection criteria: 2c.1 – 2c.2)

Provide a timetable for key project milestones (e.g. ethics approval, site/participant recruitment, completion of data collection, data analysis, final reporting). Add rows as necessary.

| # | **Key milestone** | **Achievement date (mm/yyyy)** |
|---|---|---|
| 1 | Protocol developed and ethics approval | 09/2025 |
| 2 | Site Specific Approvals | 12/2025 |
| 3 | Develop model of care | 05/2026 |
| 4 | Begin implementation and data collection | 07/2026 |
| 5 | Finalise enrolment | 06/2027 |
| 6 | Final follow-up visit | 07/2027 |
| 7 | Complete qualitative interviews | 07/2027 |
| 8 | Complete data analysis | 10/2027 |
| 9 | Disseminate and publish results | 12/2027 |

## SECTION J – PROGRAM LOGIC MODEL

This section should be no longer than 1 page.

### J.1 Please complete a program logic model for your project by filling in the table below (Selection criteria: 2e.1)

The program logic model should provide a high-level overview of the project.

Further information on program logic models can also be found in these Guidelines or via this Animation Video.

**Project Need:** Successive innovations have reduced time in hospital from as much as a week to as little as a day for many conditions. However, for those admitted with alcohol or drug withdrawal, the length of hospital stay remains 5-7 days. Inpatient stays such as this do not reflect patient preference or acceptability, and this inflexibility of services results in increased burden on the healthcare system

**Project Aims:** The primary aim of this study is to determine the effectiveness of a step-down model of care for withdrawal management to reduce service utilisation of inpatient facilities, without negatively impacting clinical outcomes or safety. The secondary aim of this study is to demonstrate the difference between the step-down model of care and treatment as usual on measures of: safety, symptom severity, hospital and health service utilisation, acceptability of the model of care and economic analysis of the model

| Activities | Outputs | End users | Outcomes |
|---|---|---|---|
| *- Establishment of committees*<br>*- Consultation with stakeholders*<br>*- Development of a model of care*<br>*- Recruitment of people withdrawing from alcohol or other drugs*<br>*- Refinement of the model of care* | *- Training package for clinicians*<br>*- New model of care* | **Implementers:**<br>*- Clinicians in hospital-based withdrawal management services*<br>*- Public hospitals with dedicated inpatient withdrawal management services and telehealth*<br><br>**Beneficiaries:**<br>*- People who use alcohol or other drugs seeking withdrawal management* | *Knowledge advancement*<br>*- Scientific evidence supporting the model of care*<br><br>*Clinical Improvement*<br>*- Increased flexibility and autonomy for those seeking withdrawal management*<br>*- Improved acceptability of services*<br>*- Maintained safety and clinical outcomes*<br><br>*Community benefits*<br>*- Improved access and accessibility of services to community*<br>*- Services better meet community needs*<br><br>*Economic Benefits*<br>*- Reduced bed days and hospital burden*<br>*- Reduced cost per patient for districts* |

**Types of impacts:** How are your findings expected to improve the outcomes of the end users (beneficiaries)? Please tick which impacts are applicable to your project and specify the anticipated impact related to the impact type in one sentence.

1. **Change in the probability of an event occurring** ☐
   *Example: reduced number of patients requiring insulin*
   Please specify impact here, if relevant:
2. **Change in the time to an event occurring** ☒
   *Example: Quicker screening process for Indigenous Patients with Type 2 Diabetes*
   Please specify impact here, if relevant: This intervention should reduce the time to discharge from hospital without negatively impacting treatment or safety of the participants
3. **Decrease costs** ☒
   *Example: reduced hospitalisation costs*
   Please specify impact here, if relevant: By reducing total bed days this intervention will reduce hospital burden and the cost associated with treating withdrawal from alcohol and other drugs in inpatient settings

## SECTION K – RESEARCH IMPLEMENTATION

This section should be no longer than 3 pages

### K.1 Implementation Handover (Selection Criteria 3.2 - 3.3, 3.7)

Once the research project is finished, there needs to be a planned implementation handover from the research team to local or state-wide implementation partners to first assess the intervention for implementation and then lead this process.

Identify which implementation partner(s) will be responsible for assessing the research findings for implementation and scaling (if relevant) from the list of partners in I.6, and which Investigator(s) from I.3 will be responsible for delivering the implementation handover to local or state-wide implementation partners. Describe how the handover will be delivered and what information will be provided to decision makers to support the case for change.

Local implementation is supported by members of the research team (CI Ezard, AIs Lintzeris, Dunlop, Haber, Collie, Fisher, Childs) who are also the clinical directors or service managers for their respective health district or network. At project end, each local lead will be provided with an overall and site-specific report containing relevant quantitative, qualitative and economic data to build an organisation-specific business case to their respective CEO for continued implementation if the findings are positive.

State-wide implementation handover will be led by Prof Ezard and Dr Acheson who will provide updates to the NSW Chief Addiction Medicine Specialist as outputs from the study become available, as well as the Centre for Alcohol and Other Drugs at the Ministry of Health. The final study report containing quantitative, qualitative and economic data will be submitted to the Chief Addiction Medicine Specialist, the Director of NSW CAOD and the chair of DACRIN so that findings may be assessed. The mix of metropolitan, regional and rural sites in the study promotes good generalisability. If acceptable, it is envisioned that learnings from the study will be incorporated into *NSW Health Guidelines for Withdrawal Management* to support state-wide dissemination.

The involvement of DACRIN, which consists of directors and study coordinators from all involved LHD/Ns, in the development of this proposal supports early awareness of the project, and updates on the project to be provided at quarterly DACRIN council meetings. Updates will also be presented at NSW Health for AOD services (including the AOD Quality In Treatment meeting), and the state wide AOD Clinical Nurse Consultant meeting. Updates will be provided by Prof Ezard, Dr Acheson, as well as Drs Clifford and Siefried who are experienced registered nurses as well as clinical academics.

### K.2 Implementation Plan (Selection criteria: 3.2 – 3.3, 3.5 – 3.6)

Implementation needs to be planned at the outset of the research design with steps put in place to ensure a smooth implementation handover.

Provide a detailed plan describing the activities that will be undertaken to implement findings that are supportive of implementation into policy and/or practice.

Activities may relate to all stages of the project; from knowledge and expertise that informs project planning and development; to dissemination of findings to relevant audiences; and ultimately the implementation of findings in policy and practice.

For each activity, identify the formal mechanisms to facilitate implementation and scaling; which partners from I.6 will be engaged, when, and how; the timing and purpose of each engagement to support successful implementation; who will be taking the lead and responsibility in driving the implementation activity; and how will the activity be funded.

| **Implementation Activity** | **Which partners will be engaged?** | **Purpose of engaging the partners** | **Indicative time this will occur** | **Who will lead this activity?** | **How will the activity be funded?** |
|---|---|---|---|---|---|
| Updates | DACRIN clinical network | Ensuring ongoing relevance of study, early recognition of | Throughout | DACRIN Coordinator | DACRIN |
| Presentation – community group | Consumers (NUAA) | Dissemination & discussion on proposed model of care | Preliminary Findings | Steele | TRG grant |
| Presentation – community group | End users – NGO | Dissemination & discussion on proposed model of care | Preliminary Findings | Acheson | TRG grant |
| Presentation – NSW CNC group | End users - nursing | Dissemination & discussion on proposed model of care | Preliminary Findings | Clifford | TRG grant |
| Presentation – Quality in Treatment | End users – medical & service management | Dissemination & discussion on proposed model of care | Preliminary Findings | Siefried | TRG Grant |
| Academic Publications | Research partners | Peer scientific review to support confidence in findings | Preliminary Findings | Acheson | NCCRED |
| National webinar – NCCRED | Research & Translation Partner | Dissemination & discussion on proposed model of care | Preliminary Findings | Acheson | NCCRED funding |
| Presentation – ACI Presentation | MOH ACI – AOD network | Dissemination & discussion on proposed model of care | Preliminary Findings | Acheson | NCCRED |
| Final Study Report | Local leads<br>Study Economist | Permits assessment of service use, acceptability and | At study end | Ezard | TRG grant |

| | | | | | |
|---|---|---|---|---|---|
| | | economic data by MoH | | | |
| Site Reports | Local leads<br>Study Economist | Permits local assessment of service use, acceptability and economic data | At study end | Ezard, Lintzeris, Dunlop Haber Collie, Fisher, Childs. | TRG grant |

**K.3 Sustainability, scalability and generalisability of results (Selection criteria: 3.1 – 3.6)**
Explain how the intervention, new model of care or process will be sustainably scaled and embedded overtime as business as usual across the system.

This new model of care can be sustainably scaled by leveraging existing infrastructure. One outcome of the COVID-19 pandemic was a sector-wide shift towards delivering a higher proportion of care via telehealth. This model proposes to leverage those newly existing telehealth services to facilitate the early discharge of withdrawal patients from inpatient wards. Because these services have been widely improved across AOD services in the state and clinicians have experience delivering care through telehealth, this model of care can easily be scaled across the state. By focusing on using pre-existing infrastructure this can be rapidly embedded within regular clinical practice. Whilst not free, the cost of delivering care via telehealth is far lower than delivering care via hospital admission. This means, if our assumptions hold true, the model will not only cover the cost of the telehealth care itself, but may also free up funds for other aspects of AOD care. The model of care therefore should fit seamlessly within the business as usual of the hospitals, as it utilises existing resources in new ways, and may reduce the overall cost of providing withdrawal management without negatively impacting patient care.

**K.4. Commercialisation and Intellectual Property (IP) arrangements (if applicable)**
Outline the commercialisation and intellectual property arrangements related to this project, if relevant

Nil

## SECTION L – BUDGET

Please provide details of requested funds and co-contributions. Grants range from $50,000 up to $500,000 over 2.5 years to 3 years.

- The requested funds should include all anticipated TRGS funding required for the research project and activities to support translation.
- For salaries of staff supporting research components of the project only, please specify the research role, salary level, maximum on-costs and their full-time equivalent hours (FTE).
- Please note that service delivery costs, including staffing, will not be funded.
- Host Organisation infrastructure charges cannot be included in the requested budget; these should be considered an in-kind contribution by the Host Organisation (L.2).

Please note the budget must be expended within 2.5 years to 3 years of issue.

### L.1 TRGS funding requested (Selection criteria: 2d.1)

| **Budget Item**† | **Funding requested (excl. GST)** | | | **Description** *(<100 words per item)* |
|---|---|---|---|---|
| | **July - Dec 2025** | **2026** | **2027** | |
| Project Coordinator [HSM2 0.8FTE] | 53,071 | 106,142 | 53,071 | Project coordinator – will assist in drafting the model of care and development of the final research proposal. Will manage the overall study and assist in conducting 28-day research follow ups. Costs reflect a HSM2 grade project coordinator at 0.8FTE for 24 months (6 months year 1, 12 months year 2, 6 months year 3) including 25% on costs |
| Site reimbursement | | 90,000 | 40,000 | Site recruitment reimbursement $387 per participant x 336 participants. Reimbursement will cover time for research activities including recruitment, consent procedures, data collection and follow up |
| Participant reimbursement | | 12,600 | 4,200 | Participant reimbursement for follow up call - $50 per follow up x 336 participants |
| Implementation science evaluation | | 30,000 | 30,000 | E/MCR implementation scientist (HSM1-2) on part-time basis to evaluate facilitators and barriers using the consolidated framework for implementation research and health economics |
| Statistical support | 8,158 | | 24,474 | Statistical support in the design and analysis of the project, including dissemination |
| Site set-up visits | 3,000 | | | Site visits by project coordinator costed at $1000 per non-metropolitan site |
| Aboriginal Researcher | 4,079 | 8,158 | 4,079 | Aboriginal Researcher to conduct research activities related to First |

| | | | | |
|---|---|---|---|---|
| | | | | Nations participants (estimated 20% of sample). Researcher will be invited to participate in the model of care development and interpreting the study findings to ensure culturally appropriate outputs |
| Consumer Researcher | 4,079 | 8,158 | 4,079 | Researcher with a lived experience of substance use to ensure community ownership of research. Researcher will be involved in developing the model of care, developing and conducting interviews and ensuring outputs reflect community perspectives |
| Consumer Advisory Group | 1,000 | 2,000 | 1,000 | Consumer Advisory Group expenses to convene and conduct regular meetings to guide the development of the model of care and analyses. Membership will include people with a lived or living experience of substance use and have Aboriginal representation |
| Dissemination costs | | | 8,500 | Open access publication/dissemination costs, presentation at one conference |
| **Total** | **$73,387** | **$257,580** | **$169,403** | **$499,848** |

† TRGS funding cannot be directed towards capital works, general maintenance costs, telephone/communication systems, basic office equipment such as desks and chairs, rent and the cost of utilities.

### L.2 Host or Partner Organisation contributions (Selection criteria: 2d.2 - 2d.3)

The Host Organisation must provide financial and in-kind support for research/implementation activities. Please insert details of cash and in-kind contributions.

**Cash Contributions**

| **Source** *Host Organisation Partner Organisation Existing Grant Funds* | **Funding provided (excl. GST)** | | | **Description** *(<100 words per item) If you have existing grant funding, please provide details and explain how TRGS funding will not duplicate* |
|---|---|---|---|---|
| | **July 2025** | **July 2026** | **July – Dec 2027** | |
| | | | | |
| | | | | |
| *Add rows as required* | | | | |
| **TOTAL** | **$** | **$** | **$** | |

**In-kind contributions**

Do not include the estimated/actual monetary value of the contribution.

| **Source** *Host or Partner Organisation* | **In-kind contribution provided** | **Description** *(<100 words per item)* |
|---|---|---|
| SVHN | | Support development of the model of care: 4 x 1 hour meetings to develop the model of |

| | | |
|---|---|---|
| | | care including a staff specialist, inpatient and outpatient nurse unit manager, peer worker and Aboriginal Health Worker<br>Research administration support including site specific approvals and study set up: HSM1 research assistant with an assumed 20 hours of work |
| SESLHD | | Support development of the model of care: 4 x 1 hour meetings to develop the model of care including a staff specialist, inpatient and outpatient nurse unit manager, peer worker ($43.07/hr) and Aboriginal Health Worker<br>Research administration support including site specific approvals and study set up: HSM1 research assistant with an assumed 20 hours of work |
| HNELHD | | Support development of the model of care: 4 x 1 hour meetings to develop the model of care including a staff specialist, inpatient and outpatient nurse unit manager, peer worker and Aboriginal Health Worker<br>Research administration support including site specific approvals and study set up: HSM1 research assistant with an assumed 20 hours of work |
| NNSWLHD | | Support development of the model of care: 4 x 1 hour meetings to develop the model of care including a staff specialist, inpatient and outpatient nurse unit manager, peer worker and Aboriginal Health Worker<br>Research administration support including site specific approvals and study set up: HSM1 research assistant with an assumed 20 hours of work |
| NBMLHD | | Support development of the model of care: 4 x 1 hour meetings to develop the model of care including a staff specialist, inpatient and outpatient nurse unit manager, peer worker and Aboriginal Health Worker<br>Research administration support including site specific approvals and study set up: HSM1 research assistant with an assumed 20 hours of work |
| CCLHD | | Support development of the model of care: 4 x 1 hour meetings to develop the model of care and implementation planning including a senior manager, inpatient nurse unit manager and Aboriginal Health Worker |

## SECTION M – CERTIFICATION BY HOST ORGANISATION

### M1. Host Organisation Certification

I certify that:

1. The Host Organisation will provide appropriate financial and in-kind support for the research.
2. All funds awarded to the Host Organisation as part of the TRGS will be used only for the purpose for which they were awarded.
3. The Host Organisation will implement the research intervention if the findings are supportive of implementation.

I understand that:

1. This Full Application will be reviewed by the Expert Review Panel and other advisors to the assessment process.
2. If alternative funding is received for this project, TRGS funding support may need to be adjusted allowing other successful TRGS applicants to be supported.

**Chief Executive Statement of Support for the Full Application (maximum 200 words)**
The Chief Executive of the Host Organisation must address the following criteria in their Statement of Support:

1. Why the problem and solution being proposed is a priority for the Host Organisation.
2. How the Chief Executive of the Host Organisation will support the research project and implementation of research findings within the Host Organisation, if there is a case for change.

_____

<Insert Name>, Chief Executive, <Insert Host Organisation Name>

_____

Date

***If this certification is not signed by the Chief Executive of the Host Organisation and the 'Request for Partnering Organisation Approval' forms are not signed by the Chief Executive of Partner Organisations for all sites where the project will be conducted, the application is not valid and will not be reviewed.***