

TRANSLATIONAL RESEARCH GRANTS SCHEME

EXPRESSION OF INTEREST

Example of a feasibility and effectiveness study

This document shows examples of key sections of the EOI form to illustrate how to meet the selection criteria. This is directly linked to the checklist available on the TRGS website:

<http://www.health.nsw.gov.au/ohmr/Pages/trgs.aspx>

- **Right question for TRGS** – Are you answering an important policy relevant question that addresses an evidence gap?
- **Right capacity and support within your organisation** – Does your organisation want to know the answer to this question and will it commit to scale up any resulting intervention if proven?
- **Right stakeholders and partners** – Have you engaged the relevant partners across the NSW health system?
- **Right mechanism for translation** – Does your intervention have the potential to be scaled up across the system?
- **Right design and method** – Can the study design answer the question with methodological rigour?
- **Right research team** – Do you have the right research skills across your team to answer the question?

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SECTION A – OVERVIEW	
Chief Investigator (applicant)	Chief Investigator
Host Organisation	LHD 1
Project title	Building capacity for child and adolescent community-based eating disorders service provision across a geographically diverse health service.
List all sites in which the project will be conducted:	<p>The project will be conducted across all five NSW LHD 1 Child and Adolescent Mental Health Service (CAMHS) community-based teams. CAMHS services are offered in LHDs throughout NSW and provide specialist mental health services to children and adolescents experiencing clinically significant mental health issues.</p> <p>While testing the feasibility, replicability and effectiveness of the treatment will take place within LHD 1, it has the potential of being scaled across other NSW LHDs. Other LHDs and a SHN are partners on the research project.</p>

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Right stakeholders and partners – Have you engaged the relevant partners across the NSW health system?

- Have you engaged partners that have the ability to implement or influence change in the system that may result from this project
- Do you have other LHDs, Specialty Health Networks, pillars, parts of NSW Health and branches within the Ministry of Health involved as partners?
(e.g. more than one LHD, a pillar, a policy branch within MoH, consumers)

SECTION A – OVERVIEW

Project partners	Position	Organisation	Contribution to project
	Director, LHD 1 Mental Health Services	LHD 1	Advice regarding model implementation in District mental health services. Support for resourcing around project governance and provision of the treatment model. Involvement will occur for project inception, facilitating implementation and monitoring progress.
	Director, Mental Health Services	LHD 2	Advice regarding model implementation in District mental health services.
	Director, Mental Health Services	LHD 3	Advice regarding model implementation in District mental health services.
	Chair	Committee overseeing the NSW Service Plan for People with Eating Disorders 2013-18.	Advice regarding scale up of the model if proven effective and dissemination mechanism through this state-wide committee
	Manager	Mental Health Branch, Ministry of Health	Advice regarding scale up of the model if proven effective and state-wide policy implications
	Manager	Kids and Families, Ministry of Health	Advice regarding scale up of the model if proven effective and state-wide policy implications
	Staff Specialist / Clinical Expert	Tertiary Metro Hospital	Expert advice regarding proposed treatment model design and appropriate translation within a geographically large LHD. Involvement will occur for project inception and at various points of implementation.
	Eating Disorder Coordinator / Clinical Expert	Tertiary Metro Hospital	Expert advice regarding proposed treatment model design and appropriate translation within a geographically large LHD. Involvement will occur for project inception and at various points of

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			implementation.
	Acting NSW Eating Disorders Coordinator	Centre for Eating and Dieting Disorders	Advice regarding the statewide policy context and LHD eating disorders service development and implementation. Involvement will occur for project inception, design, at various points of implementation and in active dissemination.
	Director	NGO focused on eating disorders	Advice regarding consumer perspective, service need and consumer engagement in planning and evaluation of the intervention. Involvement will occur for project inception and at various points of implementation.
	Executive Manager	Primary Health Network linked to LHD 1	The role of the Primary Health Network in development, implementation and evaluation of the intervention. Involvement will occur for project inception and at various points of implementation.
	Practicing General Practitioner	GP Surgery in LHD 1	The role of primary care in the development, implementation and evaluation of the intervention. Involvement will occur for project inception and at various points of implementation.
	Chief Executive	Health Education and Training Institute (HETI)	Advice on how to scale up the Family Based Therapy Training across the State.

List essential partners required for successful conduct of the project and implementation of the outcomes (e.g. LHD Director of Clinical Governance, Director of Nursing, Director of a University Research Centre)

Essential partners may include people other than Associate Investigators (see Section C.2)

Applicants are encouraged to partner with other Local Health Districts and Specialty Health Networks to improve the generalisability of research findings. Justification is required if this is not considered appropriate for the research project.

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SECTION B – ELIGIBILITY CRITERIA

B.1 Priority research

Describe why this research will answer a question that is a priority for the State and/or locally for your organisation. Include reference, to relevant State or Host Organisation strategic plans.

Right question for TRGS – Are you answering an important policy relevant question that addresses an evidence gap?

- Is your question focused on a priority health system and/or local need? (i.e. not niche)
- Will the answer to this question support the NSW health system in disease prevention, patient care or health service delivery?

Improving care for patients with eating disorders is a national, state and LHD priority.

Eating disorders have been identified as core business for NSW LHDs and all LHDs are required to develop pathways into treatment services and implement evidence-based models of care for people with an eating disorder (1). The Mental Health Commission of NSW has identified eating disorders as a clinical group requiring attention (2).

Eating Disorders are mental illnesses with multiple and often severe complications. They are associated with the highest mortality and suicide rates among people with a mental illness (3). Incidence of eating disorders appears highest in the 15-19 year age group (4, 5). Evidence-based treatment options are available and if delivered early in the course of illness, treatment can have good outcomes. Family Based Treatment for eating disorders is an effective treatment model when provided by specialist eating disorders services (6-8), and may prove a useful model to support the roll out in child and adolescent mental health settings in NSW.

In summary this project is directly linked to these strategic plans and initiatives

- All LHDs are required to develop pathways into treatment and evidence based models of care for people with an eating disorder.
- NSW Ministry of Health. NSW Service Plan for People with Eating Disorders 2013–2018. Sydney, Australia 2013.
- Mental Health Commission of NSW. Living Well, a Strategic Plan for Mental Health in NSW 2014-2024, Sydney, Australia 2013.
- LHD 1 priority strategic directions

References provided in application, not listed in this example document.

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B.2 Governance structure

Provide a brief description of the governance structure for the project, including project Steering Committee with links to the Executive structure and clinical streams of TRGS Host Organisations (150 words)

Include the research oversight function within the governance structure, identifying members of the team(s) that will steer the research from a technical perspective and note how and when they will be involved.

Right research team – Do you have the right research skills across your team to answer the question?

- Do you have senior academics on the team who will technically steer this project?

Right capacity and support within your organisation – Do you want to know the answer to this question and will committee to scale up any resulting intervention if proven?

- Is it a priority for your organisation to conduct a project in this area?
- Is there strong executive support for this project? (i.e. an executive champion who has reviewed this application)
- Does your organisation have the ability to scale up any intervention that might result from this study? (i.e. it lies within your organisation's span of control)
- Will your CEO commit to funding the scale up of this project up if it is proven successful?

A strong governance structure exists for this project. Implementation and evaluation of the proposed intervention has been ratified by the District Executive Leadership Team and project Steering Committee, the governing body for the project.

Progress of development, implementation and evaluation strategies are to be reported to the **project Steering Committee** on a 3 monthly basis. The Steering Committee comprises relevant District Executive Directors, service managers, consumers, partners, clinicians and experts. The District Director for Mental Health (project Executive Sponsor) and Clinical Director for CAMHS are both members.

An Implementation Committee will also sit underneath the Steering Committee and meet monthly to monitor implementation and evaluation of the intervention.

The **research steering committee** (made up of the investigators, representatives of partner organisations, clinical teams) will have overall responsibility for execution of the study protocol monitor implementation of the intervention, data collection, analysis plan and publications.

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SECTION C – RESEARCH TEAM

Right research team – Do you have the right research skills across your team to answer the question?

- Do you have senior academics on the team who will technically steer this project?
- Do you have a multi-disciplinary team with the right research, clinical, management and policy skills to undertake the study?
- Have your research partners worked with you to draft the methods so they are scientifically rigorous (i.e. has a senior academic reviewed the application)

C.1 Chief Investigator details

The Chief Investigator (applicant) must be employed by the Host Organisation.

Full Name	Chief Investigator
Position	Eating Disorders Coordinator
Organisation	LHD 1

C.2 Associate Investigator(s)

Include other proposed investigators in this section (maximum 10).

An investigator is expected to steer the project. Ideally the team of associate investigators needs to include senior researchers, managers, policy makers and clinicians from a range of organisations.

#	Position	Organisation	Contribution
	Research Officer	Mental Health Research Evaluation, Analysis and Dissemination (MH-READ) within LHD 1	Research design, methodology and translation into practice.
	Health Economist	MRI	Research design, methodology and overseeing health economic analysis.
	Professor	MRI	Research design, methodology and overseeing statistical analysis.
	Staff Specialist, Clinical Director	LHD 1 Child and Adolescent Mental Health Services	Child and adolescent mental health treatment and appropriate translation of a specialist model within District CAMHS teams.
	Professor	Translational Health Research Institute, University	Advise on evaluation methodology and assist with qualitative component

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SECTION D – RESEARCH PROPOSAL

D1, D2, D3

Right question for TRGS – Are you answering an important policy relevant question that addresses an evidence gap?

- Is your question focused on a priority health system and/or local need? (i.e. not niche)
- Will the answer to this question support the NSW health system in disease prevention, patient care or health service delivery?
- Is your question answering an evidence gap? (i.e. does your application have a review of the available research in the field, to show you are building on the cumulative science?)
- Is your question is focused on testing a clearly defined intervention that has the potential to improve upon current practice in NSW?
- Is there an evidence-based rationale for why the intervention you want to test might work and why it is better than other available interventions?
- Can this question be answered within two years?

D.1 Describe the problem and outline the existing evidence that you have considered before developing this proposal (300 words)

Eating Disorders are mental illnesses with multiple and often severe complications and are associated with high mortality and suicide rates (1). Comorbidity is common, illness burden is high and economic costs arising from eating disorders are substantial (2-5). Around 4% of the Australian population is affected to clinically significant levels and incidence appears highest in the 15-19 year age group (6-8). Timely and appropriate care provision may reduce morbidity and mortality, improve treatment outcomes and moderate the need to utilise other parts of the health system (9-10). Eating disorders have been identified as core business for NSW Local Health Districts (LHDs), with LHDs required to implement evidence-based treatments.

There is currently no standardised eating disorders treatment within Child and Adolescent Mental Health Services, resulting in clinical variation across LHD 1 and NSW . Given the mortality associated with illness and the variability in modality, intensity and delivery of existing treatment, there is a pressing need for a standardised evidence-based treatment. Family Based Therapy (FBT) is an effective treatment model when provided by specialist eating disorders services (11-13). There are currently no FBT programs within LHD 1 and limited evidence exists for FBT in mainstream CAMHS services.

There are accessible mainstream child and adolescent mental health services (CAMHS) services across the District, which provides a framework to test the feasibility and effectiveness of FBT across LHD 1. Knowledge of effectiveness and local and external factors that may influence uptake and delivery, patient health outcomes and cost effectiveness is required to facilitate integration into the wider health system. This research is highly relevant to implementation of the Service Plan and will provide replicability and effectiveness data to explore whether FBT can be embedded within and translated to mainstream CAMHS teams across a geographically diverse District.

References provided in application, not listed in this example document.

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D.2 What is the research question to address the problem? (100 words)

- 1) Does implementation of standardised District-wide FBT treatment in community-based CAMHS teams lead to effective and cost-effective improvements in patient outcomes?
- 2) Do specific clinician or organisational factors influence translation of FBT from a specialist treatment to a more mainstream treatment model within District Child and Adolescent Mental Health (CAMHS) teams?

D.3 Indicate where, on the research translation path, current evidence exists and where this proposal sits.

Refer to the Translational Research Framework, available on the TRGS website.¹

	Idea generation	Feasibility	Efficacy	Replicability and adaptability	Effectiveness	Scalability	Monitoring
Current evidence		X	X				
Proposed research		X	X	X			

¹ Sax Institute, Translational Research Framework: Testing innovation in policy, programs and service delivery, 2016. Available from <http://www.health.nsw.gov.au/ohmr/Documents/trgs-round2-translational-research-framework.pdf>

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D4, D5

Right design and method – Can the study design answer the question with methodological rigour?

- Is the study design matched to the research question?
- Are the methods rigorous in terms of sampling, statistical analysis and the selection and measurement of outcomes? (e.g. objective outcomes are better than self-reported outcomes)
For more detail see the [Translational Research Framework](#)
- Do you have costings or some kind of health economic analysis included that is matched to your question? (e.g. if assessing feasibility then costings, if assessing effectiveness then cost-effectiveness)

D.4 Describe the approach, including research design and methods (500 words)

Include details such as study design, intervention, sample and setting including control group where appropriate, primary and secondary outcomes, data sources/research tools, data collection methods including time points for baseline and follow up periods, sample size and power calculations, statistical analysis plan.

Study design, sample and setting

This is a before-after designed study, using an historical control group of usual treatment (TAU) and an intervention group where patients will receive FBT treatment. The sample will be all children and adolescents (aged 5-17 years) with an eating disorder diagnosis (based on DSM-5 criteria) attending any LHD 1 community-based CAMHS team within the project period with control and intervention period and samples define as:

1: Before: data collection for CAMHS treatment as usual (control group) - patient outcomes baseline, 3 and 6 months; clinician measures.

2. Implementation - provision of specialist FBT training; FBT supervision; resources to CAMHS clinicians.

3: After: data collection for CAMHS FBT treatment (intervention group) - patient outcomes baseline, 3 and 6 months; clinician measures.

Intervention: FBT CAMHS model

The study intervention involves two components. The first component of the intervention is an evidence-based eating disorders training package, including the following tiers:

1. One day face-to-face Foundational Skills training (identification, screening, assessment, basic knowledge of evidence-base, referral pathways).
2. Advanced treatment training.
3. Expert clinician development

The second component of the intervention will be delivery of resources including a detailed Model of Care, continuous quality improvement

Outcomes and tools

Patient Factors: Change in patient symptomatology and quality of life will be measured via validated self-report questionnaires completed by children (12 – 17ys) or carers/clinicians (5 -12 yrs); objective measurements and health records. Primary outcome is change in eating disorders psychopathology will be measured using the Eating Disorders Examination Questionnaire (EDE-Q). Other outcomes include: diagnosis, length of illness, % expected body weight, treatment exposure/dose, depression, anxiety

Clinician Factors: primary outcome is knowledge of core standardised treatment components. Others include: Behaviour - independent rating of audio-taped therapy sessions

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Intervention: FBT CAMHS model

The study intervention involves two components. The first component of the intervention is an evidence-based eating disorders training package, including the following tiers:

4. One day face-to-face Foundational Skills training (identification, screening, assessment, basic knowledge of evidence-base, referral pathways).
5. Advanced treatment training.
6. Expert clinician development

The second component of the intervention will be delivery of resources including a detailed Model of Care, continuous quality improvement

Outcomes and tools

Patient Factors: Change in patient symptomatology and quality of life will be measured via validated self-report questionnaires completed by children (12 – 17ys) or carers/clinicians (5 -12 yrs); objective measurements and health records. Primary outcome is change in eating disorders psychopathology will be measured using the Eating Disorders Examination Questionnaire (EDE-Q). Other outcomes include: diagnosis, length of illness, % expected body weight, treatment exposure/dose, depression, anxiety

Clinician Factors: primary outcome is knowledge of core standardised treatment components. Others include: Behaviour - independent rating of audio-taped therapy sessions

Process, economic and feasibility components

Prior to implementation, and throughout the study, the acceptability of treatment and contextual factors that may influence program uptake and delivery will be explored with stakeholders (consumers, managers, clinicians) through focus groups and surveys

- Program reach, adoption and utilisation, and circumstances in which the intervention could be successfully and routinely reproduced will be assessed through audit of health records and interviews
- Economic evaluation will comprise a trial-based cost-utility analysis investigating whether the new intervention is more cost-effective than preceding practice. The perspective of analysis will include health care system and direct patient cost

Statistical Analysis Plan and Power Calculation

This is a before (control)–after (intervention) linear mixed model design with change in improvement in the EDE-Q as the primary outcome, with clustering on the clinician.

With the EDE-Q as primary outcome, at 80% power and $\alpha=0.05$, and accounting for clustering by clinician, 43 clients in each group would be adequate to detect a moderate effect size, with a Cohen's d of 0.5.

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D.5 Provide the rationale for the approach and any potential barriers and mitigation strategies. List key approvals that will be required before the research project can proceed, i.e. ethics and governance approvals (200 words)

There is variation across eating disorders diagnostic criteria and geographical diversity across the health service. While a randomised controlled trial was not considered a practical method for evaluation, a pre-post linear mixed model design was chosen. This will require ethics approval.

Specialised knowledge and skill in eating disorders treatment provision should facilitate clinical improvement and reduce health costs (1). Poor system support has been associated with poor treatment fidelity (2,3). Implementation of FBT into routine clinical practice will focus on strong governance, workforce development and monitoring adherence.

The support of the District Executive Leadership Team and project Steering Committee provides a strong governance structure for this study. Progress of implementation and evaluation strategies are to be reported to the project Steering Committee 3 monthly. The Steering Committee comprises relevant District Executive Directors, service managers, consumers, partners, clinicians and experts. The District Director for Mental Health (project Executive Sponsor) and CAMHS Clinical Director are both members. An Implementation Committee will sit underneath the Steering Committee and meet monthly to monitor progress.

Technical aspects of the project will require specialised advice. Personnel with expertise in study design, statistics and health economics have been included in our study team and form a research steering committee.

References provided in application, not listed in this example document.

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D.6 Describe consideration given to scalability and value for money of your research project and outcome (150 words)

Right mechanism for translation – Does your intervention have the potential to be scaled up across the system?

- Is the intervention you are testing feasible for larger scale up across the NSW health system (i.e. it is cost effective and relevant to the whole system)
- Have you identified existing state-wide initiatives that your intervention can be scaled up through?

Consultation has shown significant variation in access to services and evidence-based treatment across the District and NSW. This study will explore the effects of this treatment delivered by CAMHS teams across a large geographical area and results from this study will be generalisable to other LHDs.

If successful, the feasibility, process and economic components of this study will yield data to inform policy and program development on a geographically large scale and may prove useful for implementation in other NSW LHDs. Outputs to support implementation will be developed as part of this project including:

- new District-wide evidence-based treatment program manual
- documents and presentations: Model of Care for treatment services; quality control system to ensure appropriate feedback to staff; guideline for LHDs
- a guideline will be developed to facilitate implementation in other LHDs.
- if the evaluation identifies the intervention to be cost effective, the economic analysis will inform the resources required for rolling out the intervention into other LHDs.

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D.7 What new or relevant evidence will the research project generate for policy and/or practice? What are the likely impacts of the results of the project on disease prevention at a population level, individual patient care or health service delivery? (300 words)

Right question for TRGS – Are you answering an important policy relevant question that addresses an evidence gap?

- Is your question focused on a priority health system and/or local need? (i.e. not niche)
- Will the answer to this question support the NSW health system in disease prevention, patient care or health service delivery?
- Is your question answering an evidence gap? (i.e. does your application have a review of the available research in the field, to show you are building on the cumulative science?)
- Is your question is focused on testing a clearly defined intervention that has the potential to improve upon current practice in NSW?
- Is there an evidence-based rationale for why the intervention you want to test might work and why it is better than other available interventions?
- Can this question be answered within two years?

Right mechanism for translation – Does your intervention have the potential to be scaled up across the system?

- Is the intervention you are testing feasible for larger scale up across the NSW health system (i.e. it is cost effective and relevant to the whole system)
- Have you identified existing state-wide initiatives that your intervention can be scaled up through?

New evidence for policy/practice

The *NSW Service Plan for People with Eating Disorders 2013-2018* provides direction to LHDs to ensure access to evidence-based treatments for people with an eating disorder. Evidence to support effective models of care to roll out across Districts are, however, limited.

FBT for eating disorders has proved to be an effective treatment when provided by specialist eating disorders treatment centres. This study aims to explore whether an evidence-based treatment can be embedded within and translated to mainstream community-based CAMHS teams across a District. A guideline will be developed to facilitate implementation in other LHDs.

Impact on health service delivery

If successful, this may prove useful for state-wide policy development and practice, and improve health service delivery on a large scale. This will reduce burden on specialist services and increase patient and family access to care.

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D.8 Comment on the extent to which anticipated outcomes from the research can be generalised, scaled, translated or embedded into practice. How will you ensure this occurs? (300 words)

In this section include details such as the mechanism/vehicle by which the research findings can be translated into change (e.g. communication with state and local decision maker, funder, committee, network, agency), key stakeholders that you will engage with to scale up your research (e.g. MoH, ACI, CEC, eHealth NSW, HETI, state-wide clinical networks, other LHDs/speciality networks), how the results of your study can support or integrate with existing State or regional initiatives or health services.

Right mechanism for translation – Does your intervention have the potential to be scaled up across the system?

- Is the intervention you are testing feasible for larger scale up across the NSW health system (i.e. it is cost effective and relevant to the whole system)
- Have you identified existing state-wide initiatives that your intervention can be scaled up through?

If successful, the FBT model can be feasibly scaled up for implementation in other LHDs and embedded into routine practice within CAMHS.

The evaluation will assess whether the intervention sustains positive outcomes once integrated into the health system. This will include investigating governance and implementation activities and monitoring clinician fidelity to the model, clinical outcomes and patient and parent/carer service satisfaction. The economic analysis will provide policy relevant information on cost effectiveness, and identify the resources required for up scaling the intervention.

The policy partners on this project from Ministry of Health, LHDs, Chair of the state-wide eating disorders committee and NGOs are able to support the state-wide scale up of this model if it is proven effective. The CE of the participating LHD namely will support the sustainability of this model across the District. Specific mechanism to scale this up are:

- The NSW Eating Disorders Coordinator is the central point for evidence-based translation in NSW LHDs.
- The study will be presented to the NSW Child and Youth Mental Health sub-committee and the CAMHS community benchmarking forum allowing for engagement of other LHD CAMHS Directors and support for translation.
- Committee overseeing the NSW Service Plan for People with Eating Disorders 2013-18.
- The Director of the NGO (the National Consumer Organisation) will provide advice regarding the consumer perspective around service need and engagement in scaling this up if proven successful
- HETI to consider how to best conduct FBT training across the state.

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D.9 Describe how stakeholders have been involved in the development of the research proposal and how they will continue to be involved in implementing the research outcomes (300 words)

This might include clinicians, consumers, policy makers, community and patient groups, and others

Right stakeholders and partners – Have you engaged the relevant partners across the NSW health system?

- Have you engaged partners that have the ability to implement or influence change in the system that may result from this project
- Do you have other LHDs, Specialty Health Networks, pillars, parts of NSW Health and branches within the Ministry of Health involved as partners?
(e.g. more than one LHD, a pillar, a policy branch within MoH, consumers)

Key stakeholders have been involved in identifying current treatment issues within health services, development of the proposed intervention and suggested evaluation.

Stakeholders will be actively involved in shaping project development, implementation and evaluation, and include:

- Consumers, including patients with an eating disorder and their families and carers, the LHD Mental Health Consumer Participation Unit and the NGO (a national consumer organisation). In line with the *Living Well a Strategic Plan for Mental Health in NSW 2014-2024*, consumers will be actively involved in shaping the development, implementation and evaluation of the project.
- The NSW Centre for Eating and Dieting Disorders (CEDD) reports to the NSW Ministry of Health regarding NSW Eating Disorders Service Plan implementation. CEDD will be actively involved in advice around NSW policy and translational aspects of LHD treatment implementation.
- Specialists in child and adolescent eating disorders treatment at the Metro Tertiary Hospital will provide expert advice regarding design of the proposed treatment model and appropriate translation within a geographically large LHD.
- LHD clinicians working with children and adolescents with an eating disorder and their families/carers (in inpatient and community-based services) will be involved in project development, implementation and evaluation.
- District Directors and service managers will be involved in facilitating implementation and evaluation of the intervention, and providing support for resourcing around project governance and provision of the treatment model.
- Clinicians working in non-government organisations, such as General Practitioners and the Primary Health Network will be involved in supporting development, implementation and evaluation.
- Research Stakeholders, including a biostatistician and health economist, will provide advice around research design and methodology.

Many of the key stakeholders are members of the governance structure for this project and will oversee implementation, evaluation and sustainability.