

Involving Consumers in Health and Medical Research

A practical handbook for organisations, researchers, consumers and funders.



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The value of involving consumers in health and medical research cannot be underestimated.

Consumer Involvement brings a unique perspective to all areas of research including planning, policy, funding, evaluation and reporting, as well as participation in the research project.

Extensive research in Australia and internationally provides compelling evidence that the involvement of consumers in health and medical research achieves many benefits.

These benefits are recognised across the world by governments, research bodies and health organisations that are fostering involvement of consumers through legislation, policies and financial investment.

Consumer Involvement:

- increases the relevance and responsiveness of research to health needs
- improves the quality of research and its impact on health outcomes
- strengthens the effective translation of research into policy and practice
- builds public confidence in health and medical research
- increases opportunities for research funding

As primary stakeholders, consumers have an inherent right to be involved in health and medical research and should be encouraged, supported and given opportunities to do so.

“This Handbook is the essential resource for all those who are serious about involving consumers in health and medical research.”

Professor Gary Geelhoed MBBS, FRACP, FACEM, MD
Immediate Past Chair AHRA
Executive Director WAHTN

This handbook has been developed by the Western Australian Health Research Alliance (WAHTN) as part of the Australian Health Research Alliance (AHRA) National Consumer and Community (CCI) Initiative.

The purpose of the WAHTN is to facilitate and accelerate health research translation. It operates as a unique partnership between WA's universities, medical research institutes, the WA Department of Health and its agencies and the private health sector.

AHRA facilitates the integration of healthcare, health and medical research, and health professional education to deliver better health outcomes for all Australians.

Its members comprise seven accredited Advanced Health Research and Translation Centres and three Centres for Innovation in Regional Health, which collectively encompass over 90% of researchers and 80% of acute health care services in the country.

Always Was: Always Will Be. We acknowledge the Aboriginal people as the traditional custodians of this land. We recognise the enduring connection with the land, water and skies and pay respect to elders, past and present.

Four Stakeholders: A Unique Symbiosis

Consumer Involvement has been largely focused on Researchers and Consumers as the two key stakeholders.

This Handbook recognises four stakeholders in the Consumer and Community Involvement (CCI) ecosystem: Organisations, Researchers, Consumers and Funders.



The unique symbiotic relationship between these stakeholders is at the heart of successful consumer involvement.

Meaningful and effective involvement is underpinned by four important principles:

- **Power** shared between the stakeholders
- **Trust** between the stakeholders
- **Belief** that meaningful involvement adds value
- **Understanding** of each other's roles, responsibilities and mutual obligations

Why a Handbook?

This Handbook complements the rich suite of consumer involvement research, frameworks, policies and toolkits that have been developed by governments and organisations Australia-wide and internationally. All provide strong foundations and guidance for implementing consumer involvement.

It addresses a key barrier to embedding CCI: how to start.



This Handbook – A Practical Guide

This Handbook is designed for ease of access by each of the four stakeholders. However, to achieve effective consumer involvement, it is critical that the four stakeholders understand each other's roles and mutual obligations. Familiarisation with all of the steps and resources at the start will greatly assist this.

It is designed to be adaptable and users are encouraged to make it their own, to suit their particular needs and circumstances.

This Handbook provides a step-by-step approach to embedding CCI in organisations involved in health and medical research

The Five Phases

There are five critical phases, relevant to all the stakeholders, for successful embedding of Consumer Involvement:

- Phase 1** – Commitment
- Phase 2** – Planning and Preparation
- Phase 3** – Managing for Success
- Phase 4** – Evaluating the Involvement
- Phase 5** – Concluding the Involvement

The Steps

Clear steps for each phase for each stakeholder

The Tools

Each step is supported by practical resources

Other Resources

Library of links to other useful resources

“When consumers are included as a valued part of the team, they provide a different way of looking at the research which benefits the researcher, the research organisation and, ultimately, the health consumer.”

George Kiosoglou
Consumer Representative
WEHI and Melbourne Academic
Centre of Health

The Handbook: Part 1 Step by Step

Steps for Organisations Moving from good intentions to good practice	7
Steps for Researchers Getting the most out of the consumer's involvement	9
Steps for Consumers Adding meaningful value to health and medical research	11
Steps for Funders Leading by example	13

The Handbook: Part 2 Resources

Phase 1 Resources Commitment	16
Phase 2 Resources Planning and Preparation	28
Phase 3 Resources Managing for Success	39
Phase 4 Resources Evaluating the Involvement	46
Phase 5 Resources Concluding the Involvement	49
Library Handy Links	52
Full List of Resources	56

Definitions

This Handbook uses the definitions from the Australian National Health and Medical Research Council (NHMRC) and the Consumers Health Forum of Australia's Statement on Consumer and Community Participation in Health and Medical Research.

Consumer and Community Involvement (CCI)

This is a common term used almost universally to describe Consumer and Community Involvement in research. Whilst this Handbook focuses more specifically on Consumer Involvement, the term CCI is used for consistency.

Involvement

In this Handbook, Involvement describes the many and varied arrangements through which consumers participate meaningfully in all aspects of health and medical research (refer to Resource 2 in this Handbook). This Handbook refers specifically to Consumer Involvement in research and related activities. Whilst there may be elements that are also relevant to Consumer Involvement in the planning and delivery of healthcare services, this is not the primary purpose of this Handbook.

Consumers

Consumers are patients and potential patients, carers, organisations representing consumers' interests, members of the public who are targets of health promotion programs and groups asking for research because they believe that they have been exposed to potentially harmful circumstances, products or services.

Organisations

Formal and/or legal entities that undertake health and medical research including, but not limited to, medical research institutes academic institutions, health services and hospitals.

Researchers

Those who undertake approved health and medical research including, but not limited to, academic researchers, clinicians, undergraduate and postgraduate students.

Funders

Formal and/or legal entities that support health and medical research through funding, grants, sponsorship, donations and investments.

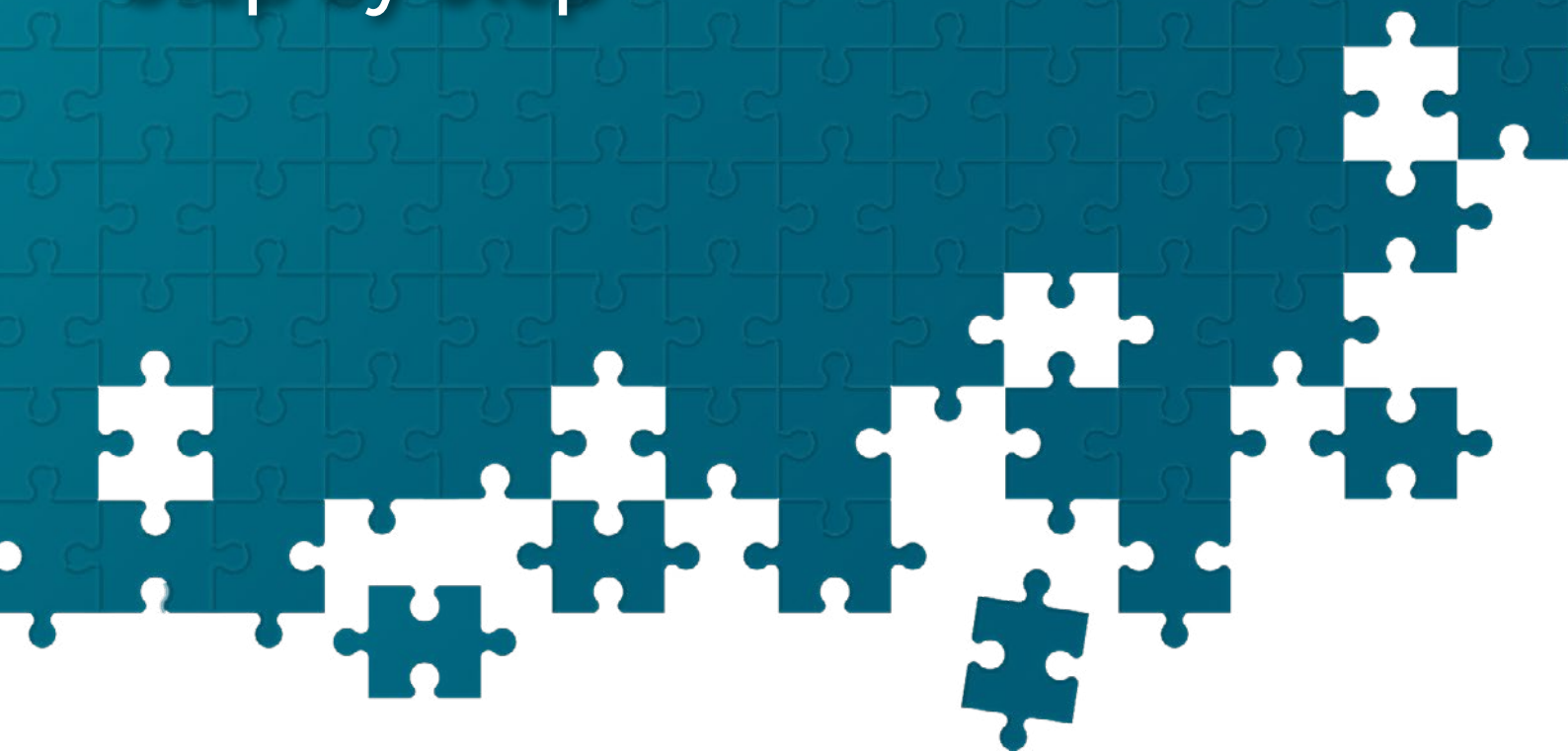
“Health research is about asking questions to uncover new information and improve outcomes. In that process, what consumers want and what researchers want is the same – ensuring that we ask the most important questions, and then bring the best available answers to the bedside. When this occurs as a partnership through the entire research process, the benefit and impact will be maximised.”

| Associate Professor Ed Litton, Intensive Care Specialist (Fiona Stanley Hospital)
and National Health and Medical Research Council Early Career Research Fellow



The Handbook: Part 1

Step by Step



This section provides concise implementation steps for each stakeholder:



Organisation



Researcher



Consumer



Funder





Adding meaningful value to health and medical research

The voice, experience, knowledge and perspective of the consumer, when harnessed well, can transform the quality and relevance of health and medical research.

Achieving this requires empowered, informed and well-prepared consumers, able to meet this responsibility and confident that they are the right person in the right role at the right time.

Step	Description	Resource
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PHASE 1: Commitment

Step 1	Understand CCI – latest thinking, potential benefits and types of involvement	Resource 1: Overview of CCI
Step 2	Be clear about your motivation for involvement and what you want from it	Resource 8: Consumers: Why Get Involved in Research
Step 3	Consider the variety of ways that you can be involved	Resource 2: Types of Involvement
Step 4	Investigate the health and medical research organisations that involve consumers and which interest you	Resource 3: Organisations Leading Consumer Involvement

PHASE 2: Planning and Preparation

Step 5a	<ul style="list-style-type: none">• join consumer health organisations and/or subscribe to their newsletters etc.• register your interest with health research organisations• approach an organisation directly to express your interest	Resource 19: Consumers: Approaching an Organisation
Step 5b	Ensure you make an informed choice about the organisation and research program before you commit	Resource 20: Consumers: Assessing the Opportunity

PHASE 3: Managing for Success

Step 6	<ul style="list-style-type: none"> • ensure that your involvement arrangement is clarified through a suitable document e.g. Involvement Agreement, Terms of Reference, Letter of Agreement • clarify the remuneration process • clarify requirements and expectations, including yours • communicate regularly with the researcher or the key organisation contact or mentor • use the Involvement Agreement to guide periodic catch-ups and amend the Agreement as necessary 	<p>Resource 21: <i>Committee Terms of Reference</i></p> <p>Resource 22: <i>The Involvement Agreement</i></p> <p>Resource 24: <i>Remuneration Claim Form</i></p> <p>Resource 25: <i>Managing for Success</i></p> <p>Resource 26: <i>Managing for Success</i></p>
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PHASE 4: Evaluating the Involvement

Step 7	<ul style="list-style-type: none"> • participate in the evaluation of the involvement • your contribution is important and will inform how you approach future involvement arrangements 	<p>Resource 27: <i>Evaluating the Involvement</i></p>
Step 8	<ul style="list-style-type: none"> • take time to reflect on the involvement • consider learnings • make changes 	<p>Resource 28: <i>Reflecting on the Involvement</i></p>

PHASE 5: Concluding the Involvement

Step 9a	<p>Planned Conclusion:</p> <ul style="list-style-type: none"> • acknowledge the opportunity for the involvement • celebrate shared success • create channels for potential future involvement • ensure that your contribution has been appropriately acknowledged on all reports, documents and/or presentations 	<p>Resource 29: <i>Concluding the Involvement – Planned</i></p>
Step 9b	<p>Unplanned Conclusion:</p> <ul style="list-style-type: none"> • protect any benefits that have been achieved • minimise any adverse impact of an unplanned ending to involvement 	<p>Resource 30: <i>Concluding the Involvement – Unplanned</i></p>

The Handbook: Part 2

Resources



This section provides the practical resources for each of the steps. They are colour-coded for easy reference:

● **ORGANISATIONS** ● **RESEARCHERS** ● **CONSUMERS** ● **FUNDERS**

Resources are arranged within the five phases:

- | | |
|---------|----------------------------|
| Phase 1 | Commitment |
| Phase 2 | Planning and Preparation |
| Phase 3 | Managing for Success |
| Phase 4 | Evaluating the Involvement |
| Phase 5 | Concluding the Involvement |

Phase 1 Resources

Commitment

Resource 1:	Overview of CCI	● ● ● ●	Pg 17
Resource 2:	Types of Involvement	● ● ● ●	Pg 18
Resource 3:	Organisations Leading Consumer Involvement	● ●	Pg 20
Resource 4:	CCI Policy for Organisations	●	Pg 21
Resource 5:	Policy Checklist	● ●	Pg 22
Resource 6:	Communication to Stakeholders	● ●	Pg 23
Resource 7:	Researchers: Why Involve Consumers in Research Projects	●	Pg 24
Resource 8:	Consumers: Why Get Involved in Research	●	Pg 25
Resource 9:	Involving Consumers in Funder Activities	●	Pg 26
Resource 10:	CCI Policy for Funders	●	Pg 27

Resource 1: Overview of CCI



CCI: What's it all about?

The following documents provide a contemporary overview of CCI relevant for organisations, researchers, consumers and funders.

Direct discussions with consumers and/or consumer organisations will also be highly beneficial. (Refer to Resource 3)

This is a dynamic environment and users are encouraged to add to, and update this list with relevant material as it is published.

Contemporary information about CCI

The Statement on Consumer and Community Involvement in Health and Medical Research (2016) NHMRC

- <https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research>

Consumer and Community Involvement in Health and Medical Research: An Australia-wide Audit

- https://www.wahtn.org/wp-content/uploads/2019/03/AHRA-CCI_Final-Report_Full_Dec2018.pdf

South Australian Health and Medical Research Institute (SAHMRI) Framework

- https://www.sahmri.org/m/downloads/20140606_Health_Consumers_in_Research_Report_FINAL.pdf

South Australian Health and Medical Research Institute (SAHMRI) Value Statement

- <https://healthtranslationsa.org.au/wp-content/uploads/2020/11/The-value-of-CCI-report-v2.pdf>

Cancer Australia: National Framework for Consumer Involvement in Cancer Control

- https://www.canceraustralia.gov.au/sites/default/files/publications/national_consumer_framework_web_504af020f2184.pdf

Miller et al (2017), Integrating consumer engagement in health and medical research – an Australian framework

- <https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-017-0171-2>

“Why should it be up to researchers who have no experience personally with a particular disease to decide what a study design should look like or what outcomes should be measured?”

| Dr Susan Kahn, Associate Director for Clinical Research
| at the Lady Davis Institute in Montreal



The power of a lived experience and so much more

Consumers provide a unique perspective to all aspects of the planning and delivery of quality research. This table lists many of the possible ways of involving consumers. It is not exhaustive and users are encouraged to continue to explore other involvement opportunities.

Ways in which consumers can be involved in research

Within Government, Health Sector Bodies	<ul style="list-style-type: none"> • membership on government advisory or planning or policy bodies • membership of consumer health sector advisory or planning or policy bodies • participation in periodic health research forums and workshops conducted by these bodies
Within the Research Organisation	<p>Membership of organisational groups e.g.</p> <ul style="list-style-type: none"> • Board • Board Sub-committee • Research Advisory Committee • Consumer Advisory Committee • Fundraising Committee • Ethics Committee • assessment panels for funding applications in organisations • Consumer Focus Group • Consumer Reference Group <p>One-off input into:</p> <ul style="list-style-type: none"> • relevant policies e.g. Consumer Involvement Policy • Strategic Plan • planning research program, agenda and priorities • reviews of Consumer Involvement • sharing the lived experience to inform policy, practice, marketing, fundraising • specialist consumer advisor • research ambassador or champion
Delivering the Research Project	<p>Involvement as a member of a research team including, but not limited to:</p> <ul style="list-style-type: none"> • sharing lived experience to shape the research scope, design and plan • designing the research project and developing a project plan • preparing grant applications and proposals • presenting research proposals to funders and donors • linking the researchers to community and consumer groups • collecting research information and data • analysing and reviewing data • writing or reviewing research reports • assisting with plain English writing • presenting research reports at forums, workshops and conferences • translating research findings to improve clinical practice and health <p>Membership of project-specific groups e.g.</p> <ul style="list-style-type: none"> • Focus Group • Reference Group • Advisory Group

Resource 2: Types of Involvement (Cont.)

Participating in the Research	<ul style="list-style-type: none">• participating in clinical trials• attending clinics where the consumer information is used for research• being a study subject in a research project
Research Funding	<ul style="list-style-type: none">• clarifying research needs and priorities• liaising with consumer groups• developing funding policies• designing funding/grants programs• determining program goals• designing program evaluation• evaluating the program(s)• designing internal and external communications• championing the programs in the community• designing application forms and processes• designing assessment tools and criteria <p>Participating on e.g.</p> <ul style="list-style-type: none">• assessment panels• shortlisting panels• review panels• advisory panels• evaluation panels



The go-to organisations for CCI

A range of organisations in Australia support Consumer Involvement in health and medical research. The lists below provide an important starting place for exploring potential consumer involvement.

Organisations that provide consumer involvement opportunities

Health Consumer Organisations / Networks

Health consumer organisations and networks in Australia provide information, support, links to health research organisations and training for consumers. As a consumer, you may consider joining one of these to access resources and opportunities:

- Consumer and Community Involvement Program
<https://cciprogram.org/>
- Consumers Health Forum of Australia
<https://chf.org.au/>
- Health Care Consumers' Association
<https://www.hcca.org.au/>
- Health Consumers Council
<https://www.hconc.org.au/>
- Health Consumers NSW
<https://www.hcnsw.org.au/>
- Health Consumers Queensland (HCQ)
www.hcq.org.au
- Meeting for Minds
<https://meetingforminds.com/>
- Safer Care Victoria
<https://www.bettersafercare.vic.gov.au/>

You can also search for involvement opportunities in the following areas:

• **Specific Diseases**

There are many disease-specific organisations that can link you to researchers, policy makers and funders e.g. Cancer Council Australia, the Heart Foundation, Dementia Australia Limited, Rare Voices Australia.

• **Medical Research Institutes**

These exist in every Australian state/territory. Some are disease specific but most have a broader research scope. Many have consumer registers.

• **Universities**

Universities undertake a large proportion of Australia's health and medical research.

• **Hospitals**

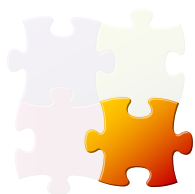
Hospitals undertake research and provide opportunities for involvement in research and healthcare quality.

• **Australian Health Research Translation Centre (AHRTCs) and Centres for Innovation in Regional Health (CIRHs)**

These represent over 90% of health and medical researchers:

- Brisbane Diamantina Health Partners
<https://brisbanediamantina.com/>
- Central Australia Academic Health Science Network
<http://caahsn.org.au/>
- Health Translation SA
<https://healthtranslationsa.org.au/>
- Maridulu Budyari Gumal – Sydney Partnership for Health, Education, Research and Enterprise (SPHERE)
<https://www.thesphere.com.au/>
- Melbourne Academic Centre for Health
<https://www.machaustralia.org/>
- Monash Partners
<https://monashpartners.org.au/>
- NSW Regional Health Partners
<https://nswregionalhealthpartners.org.au/>
- Sydney Health Partners
<https://sydneyhealthpartners.org.au/>
- Tropical Australian Academic Health Centre
<https://www.taahc.org.au/>
- Western Australian Health Translation Network
<https://wahn.org/>

Resource 8: Consumer: Why Get Involved in Research



“What’s my reason for being involved in research?”

It is critical for consumers to be clear about their reasons for being involved in research. This will ensure the best possible involvement experience for the consumer and maximise the success of the research. The checklist below provides a useful starting point.

Clarifying consumer reasons for getting involved

Rating					
1 Not Important	2 Desirable	3 Important	4 Very Important	5 Critical	
	1	2	3	4	5
Use my acquired skills and expertise					
Use my experience of a disease/health condition to inform and enhance research					
Be involved with and contribute to a particular organisation					
Be involved with and contribute to knowledge about a particular disease or health condition					
Find a meaningful volunteer role					
Learn more about a disease/health condition					
Learn more about research					
Earn income					
To give something back and to make a difference					
Develop my skills					
Be a voice for others					
Meet new people, share experiences					
Turn a negative experience into a positive outcome					

Phase 2 Resources

Planning and Preparation

Resource 11:	Creating a CCI Culture	● ● ●	Pg 29
Resource 12:	Involvement Costs and Considerations	● ● ●	Pg 30
Resource 13:	CCI Coordinator Role	● ● ●	Pg 31
Resource 14:	Recruiting Consumers	● ● ●	Pg 32
Resource 15:	Interviewing Potential Consumers	● ● ●	Pg 33
Resource 16:	Setting up a Consumer Register	● ● ●	Pg 34
Resource 17:	Request for Expression of Interest	● ● ●	Pg 35
Resource 18:	The Role of the Mentor	● ● ●	Pg 36
Resource 19:	Consumer Approaching an Organisation	●	Pg 37
Resource 20:	Consumer Assessing the Opportunity	●	Pg 38



Taking the initiative

Consumers can take the initiative and approach research organisations themselves. Here are some strategies for this.

Consumer - tips for approaching an organisation

1. Initial Contact

Consider any or all of these strategies:

- telephone the organisation
- email the organisation
- attend any community information forums that the organisation holds
- ask a consumer health network to provide an introduction to the organisation (the network may have contacts there)

2. Communication

In all your communication ensure that you provide important basic information including:

- that you are a consumer
- why you are contacting the organisation
- your interest in becoming involved in the organisation's research
- the type of involvement you are keen to pursue
- interest in meeting with them or sending them a brief summary about yourself

3. Follow Through

Prepare a brief bio or statement about yourself that you can provide as a follow-up to the initial contact. It should be no more than one page long and include:

- name and contact details
- why you are contacting the organisation
- your interest in becoming involved in the organisation's research
- the type of involvement you are keen to pursue
- what you have to offer
 - knowledge
 - expertise
 - experience, including a lived experience
- any other involvement you may have had
- any special requirements you have
- any restrictions on your availability (e.g. time, location, about to go on holiday, mobility, health etc.)

Resource 20: Consumer: Assessing the Opportunity



Look before you leap

This checklist will assist consumers to make informed decisions about taking up an involvement opportunity that is offered to them.

Consumer - assessing an involvement opportunity

Considerations	Yes/No
About You	
Does the role align with my values?	
Does the role fit with my consumer aspirations?	
Is the role interesting and challenging?	
Do I have the skills and knowledge for the role e.g. IT skills, writing skills, management skills?	
Do I have the time to fulfil the role well?	
Are there any reasons why I may not be able to fulfil this role? e.g health	
What is my passion for the role?	
Am I ready for this role?	
Am I a current patient and does this involvement affect my ability to contribute?	
Will involvement in this research affect me personally and am I ready?	
What is my gut feeling?	
About the Organisation	
Have I researched the organisation and am I comfortable with it?	
Do the organisation's values align with mine?	
Has the organisation or researcher clarified why they are seeking consumer involvement?	
Has the role been made clear?	
Have I met the key people?	
Have the conditions about the involvement been made clear?	
Has remuneration been clarified?	
Do I need support to fulfil the role and is this available?	
Do I have enough information to make a confident decision?	

Phase 3 Resources

Managing for Success

Resource 21:	Committee Terms of Reference	● ● ● ●	Pg 40
Resource 22:	The Involvement Agreement	● ● ● ●	Pg 41
Resource 23:	Induction and Orientation	● ● ● ●	Pg 42
Resource 24:	Remuneration Claim Form	● ● ● ●	Pg 43
Resource 25:	Managing for Success	● ● ● ●	Pg 44
Resource 26:	Managing for Success	● ● ● ●	Pg 45



Getting on the same page

Terms of Reference clarify the purpose of a committee, advisory body, reference group etc. and help to keep activities focused. These need to be provided at the time of recruiting potential members and before they agree to join it. The following chart provides the key headings and content for Terms of Reference.

Terms of reference - key elements

1. Background

- name of organisation
- purpose of the organisation
- vision
- values

2. Name of Committee/Advisory Group/Reference Group/etc.

3. Purpose of the Committee or Group

- role of the Committee/Group
- what it is expected to deliver
- who the Committee/Group reports to
- what matters the Committee/Group considers
- any matters that the Committee/Group decides

4. Committee/Group Membership Members

- Chairperson
- Deputy Chairperson
- General Members

5. Obligations

- attendance at meetings
- preparation for meetings
- participation in meetings
- any requirements additional to attending meetings

6. Meeting Arrangements

Meeting dates, times, duration and venues

7. Remuneration (if applicable)

- hourly rate
- out-of-pocket reimbursement
- travel and parking vouchers
- member voluntary contribution

8. Term

- commencement date
- conclusion date
- any changes to the Terms of Reference

9. Contact

- key contact person for matters relating to this Committee/Group
- name, phone number and email



Put it in writing

It is critical that the involvement arrangement is captured in a suitable document so that all parties are clear about what has been agreed. The document is central to achieving the best possible involvement outcomes for all. Below is a simple template that can be easily adapted for specific situations.

Involvement agreement

1. Parties to this Agreement

Select whichever is applicable.

- a. Organisation
- b. Consumer
- c. Researcher
- d. Funder

2. Involvement Purpose

This Agreement clarifies the involvement arrangement between:

(name of consumer) and (name of organisation).

3. Type of Involvement

Refer to Resource 2: Types of Involvement

The Consumer will be involved in the following ways:

- participating in an Organisation Committee or Group
- participating in the Research Project
- participating in the Research as a study subject

4. Involvement Period

The period for this involvement commences on (date) and concludes on (date).

A new agreement will be negotiated for any further involvement.

5. Contact Person

Name of contact person for matters relating to this involvement.

6. Involvement Details

- name of the Committee/Group or Research Project
- roles and responsibilities of each party (attach)

7. Obligations

- a. the Organisation has all necessary insurances to support this involvement
- b. the project has all the necessary approvals, including ethics, to proceed
- c. the Consumer confirms that there are no legal, health or other impediments to their involvement

8. Conflict Resolution

Procedure for dealing with issues, concerns and conflict (attached or see link to Organisation's policy)

9. Changing the Agreement

Changes to this Agreement can be proposed by any of the parties but any change requires agreement by all parties.

10. Remuneration

- a. amount of cash and non-cash remuneration
- b. payment arrangements

11. Privacy and Confidentiality

- a. privacy requirements of the Consumer
- b. confidentiality requirements of the Organisation

12. Acknowledgement

Acknowledgement of the consumer and the involvement (e.g. on report, papers, documents)

13. Other Conditions

14. Signatures of Parties and Date

Additional Resource

Australian Clinical Trials Alliance (ACTA):

A useful template for a consumer involvement agreement.

<https://www.viccompncancerctr.org/about-vccc/consumer-engagement/resources/>

Resource 24: Remuneration Claim Form



Keep it simple

Keeping the remuneration process clear and simple will minimise red tape and avoid unnecessary frustration. Below is a simple claim form that meets financial accountability requirements.

Remuneration or reimbursement claim for consumer involvement activities

Consumer Details	
Name	
Address	
Email Address (for payment confirmation)	
Bank Account Details	Name
	BSB
	Account No

Type of Involvement	
Name of Research Project	
Name of Committee/Group	

Fees/Expenses			
Description	Date	Amount (\$)	Receipt provided
Total (\$)			

Taxation Considerations

Signature _____ Date _____

Please return to: _____

Additional Resources

ACTA

<https://involvementtoolkit.clinicaltrialsalliance.org.au/media/sbbhec00/toolkit-cost-calculator.xlsx>

Involve

<https://www.invo.org.uk/posttypepublication/budgeting-for-involvement/>
<https://www.invo.org.uk/resource-centre/involvement-cost-calculator/>



It's everyone's responsibility

The importance of good planning cannot be overstated. It will enable a smooth management of the involvement. The chart below summarises how each party contributes to managing it.

Managing the involvement – a shared responsibility

Organisation	Funder	Researcher	Consumer
Build and nurture the relationship, the single most important factor for successful Consumer Involvement		Deliver against the Involvement Agreement and refer to it as you go	Deliver against the Involvement Agreement and refer to it as you go
Deliver against the Involvement Agreement and refer to it as you go		Ensure one main contact person is known to the consumer and other stakeholders	Appreciate the value that you add
Adopt a proactive approach and avoid constantly putting out fires		Maintain lines of information flow between all relevant people	Adopt a proactive approach to anticipated and unexpected challenges
Incorporate the involvement in usual day-to-day operations where possible to minimise additional effort		Schedule times to discuss progress of the involvement against agreed expectations, roles, responsibilities	Establish and maintain regular communication with the named contact person or research mentor
Plan for unexpected issues and challenges		Adopt a proactive approach to anticipated and unexpected challenges	Confirm lines of information flow between all relevant people
Ensure one main contact person is known to consumers and all other key stakeholders		Communicate any changes to the research project that affect the Involvement Agreement	Participate in scheduled discussions about the progress of the involvement against the agreed expectations, roles, responsibilities
Establish clear lines of information flow and make them known		Recommend and negotiate changes to the Involvement Agreement as necessary	Communicate any changes to circumstances that affect the Involvement Agreement
Schedule times to discuss progress of the involvement against agreed expectations, roles, responsibilities		Promote opportunities for ongoing input from consumers	Negotiate and recommend changes to the Involvement Agreement as necessary
Recommend and negotiate changes to the Involvement Agreement as necessary		Build on learnings and successes	Take opportunities to provide ongoing input
Use learnings from problems and challenges for continuous improvement		Keep good records of reviews and discussions to inform reporting, evaluation and improvement	Invest in yourself and take all formal and informal learning opportunities provided – learn as much as you can
Provide opportunities for ongoing input from stakeholders			Keep good records of reviews and discussions to inform reporting, evaluation and improvement
Keep good records of reviews and discussions to inform reporting, evaluation and improvement			



Avoiding the pitfalls

Managing the involvement does not need to be complex or arduous. Below are some common pitfalls to avoid.

Common pitfalls

Lack of adequate preparation – of processes, policies and people
Rushing the process
A culture that does not understand or support involvement
Lack of an Involvement Agreement
Poor communication with internal and external stakeholders – they hear things second or third-hand
Over-focus on the long-term and ignoring the now
Lots of fanfare followed by little or no action
Ineffective, invisible or absent leadership
Over-complicating the implementation process
Failure to include the right people in the involvement process
Failure to adequately resource the involvement process
Over-focus on processes and systems at the expense of people and culture
Not addressing cynicism or resistance
Assuming that all stakeholders will see things the same way
Straying from the Involvement Agreement without the agreement of the parties
Words and actions that don't match
Lots of communication at the start followed by lack of ongoing communication
Failing to be flexible and responsive to changing circumstances – always have a Plan B

Phase 4 Resources

Evaluating the Involvement



Resource 27: Evaluating the Involvement



Pg 47

Resource 28: Reflecting on the Involvement



Pg 48





How did we perform?

This table provides a simple way of measuring the involvement experience of each party. This evaluation takes place at the end of the involvement/project. It is important that each party participates in the evaluation to provide a holistic and complete picture, which is important for continuous improvement.

Evaluating the involvement

Involvement Agreement Item	Rating			Action Required
	Low	0 – 5	High	
Was the Involvement Agreement clear, relevant and comprehensive?				
Was the purpose of the involvement achieved?				
Were the expectations met?				
Was the Consumer Involvement Policy clear, relevant and helpful?				
Were there sufficient resources to achieve optimal involvement?				
Were roles and responsibilities clear and well understood?				
Was the remuneration clear and were payment arrangements followed?				
Were any issues, concerns and conflicts addressed effectively?				
Were changes to the Involvement Agreement well managed?				
Were privacy and confidentiality arrangements clear and respected?				
Was the involvement experience positive?				
Did the involvement add value?				

Additional Resources

Cancer Australia (CA)

A resource to inform decisions about how evaluation will be best assessed and why.

https://consumerinvolvement.canceraustralia.gov.au/sites/default/files/doc-lib/accessible/service_managers/m9-46_guide_evaluationconsumerinvolvement.pdf

Australian Clinical Trials Alliance (ACTA)

Evaluating involvement from the Consumer and Researcher perspectives.

<https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/evaluating/evaluating-involvement/>

Resource 28: Reflecting on the Involvement



Did the involvement make a difference?

This table provides a simple tool for reflecting on what has been achieved by the involvement. For maximum benefit, each party should complete it to provide a holistic picture.

Reflecting on the involvement

Achievements	Describe	Learning What was learnt	Action What will we • stop doing • keep doing • start doing
Benefits achieved for the Organisation			
Benefits achieved for the Researcher			
Benefits achieved for the Consumer			
Benefits achieved for the Funder			
Benefits achieved for the Research			
Value of the involvement			
Legacy of the involvement			
How do you think the involvement has/ will improve health outcomes?			
Did the benefits achieved justify the cash and non-cash investment?			
Was it worth it?			
Does the commitment to Consumer Involvement remain?			

Additional Resources

Australian Clinical Trials Alliance (ACTA)

An alternative evaluation tool.

<https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/resources/>

Centre of Excellence on Partnership with Patients and the Public

A scorecard for evaluating Involvement.

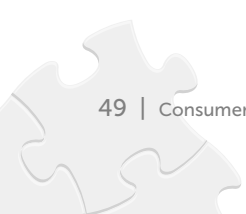
<https://ceppp.ca/en/evaluation-toolkit/a-scorecard-for-evaluating-engagement/>

Phase 5 Resources

Concluding the Involvement



Resource 29: Concluding the Involvement – Planned	● ● ● ●	Pg 50
Resource 30: Concluding the Involvement – Unplanned	● ● ● ●	Pg 51





Wrap-up and consolidate

Concluding the involvement is an important step. It wraps up the involvement experience and achievements and builds foundations for future involvement.

Concluding the involvement

Treat the ending as a normal business process and manage it accordingly
Manage the ending as a normal business process, keeping to any requirements of the Involvement Agreement
Take a professional and mutually respectful approach
Ensure appropriate acknowledgement and recognition of the consumer's contribution
Put absolutely everything in writing including notes of any verbal communications
Protect any benefits that have been achieved through the involvement
Mitigate against damage to reputation
Honour any agreements in place regarding confidentiality and privacy
Consider any future involvement opportunities and how these will be communicated
Ensure the consumer participates in the evaluation
Provide an opportunity for the consumer to provide both open and confidential feedback
Ensure that there is appropriate closure for all parties involved; don't just have the consumer just slip out unnoticed
Keep bridges intact and doors open – one does not know what the future holds
Provide a brief report to the relevant people in the organisation to keep them informed and engaged with Involvement

**MOVE FORWARD WITH
CONFIDENCE**



Manage disruption, avoid derailment, protect the benefits

An unplanned ending to an involvement may be due to:

- A serious breach of the Involvement Agreement by one of the parties
- Changing circumstances requiring the involvement to be concluded
- Unresolvable differences between the parties

The parties have invested personal, professional and organisational resources in the involvement and should seek to retain as much of the benefit as possible while minimising the risk of reputational damage to all parties.

Concluding the involvement

Treat the ending as a normal business process and manage it accordingly
Take a professional and mutually respectful approach
Act cleanly and swiftly – don't drag it out
Be aware of not wasting considerable time and resources attempting to resuscitate an unrecoverable relationship – call it when it's time
Avoid emotion-driven actions or statements
Put absolutely everything in writing including notes of any verbal communications
Mitigate against damage to reputation
Protect any positive outcomes and achievements
Take responsibility for your contribution to the involvement breakdown
Adhere to the agreements in place around intellectual property and privacy and confidentiality
Honour any agreements in place regarding confidentiality and privacy
Protect any benefits that have been achieved through the involvement
Be aware of any policies, regulations, standards and laws that may apply and ensure compliance with them
Keep bridges intact and doors open – one does not know what the future holds
Meet with key stakeholders, especially the other staff, team members and volunteers, to provide information and reassurance
If there is potential risk to reputation, advise all relevant external parties (funders, regulators, authorities) in writing

**MOVE FORWARD WITH
CONFIDENCE**

Library: Handy Links



Library 1:	Contemporary Overview of CCI	Pg 53
Library 2:	Major CCI Statements	Pg 54
Library 3:	Leading CCI Organisations	Pg 55



The development of this Handbook is preceded by AHRA's 'Consumer and Community Involvement in Health and Medical Research: An Australia-wide Audit' in 2018, which included an extensive review of CCI literature.

That report, and a selection of other publications considered both contemporary and relevant to the purpose of this Handbook, are listed here.

This is a dynamic environment and users are encouraged to add to, and update this list with relevant material as it is published.

- **AHRA 'Consumer and Community Involvement in Health and Medical Research: An Australia-wide Audit' in 2018**
https://www.wahtn.org/wp-content/uploads/2019/03/AHRA-CCI_Final-Report_Full_Dec2018.pdf
- **Cancer Australia: National Framework for Consumer Involvement in Cancer Control**
https://www.canceraustralia.gov.au/sites/default/files/publications/national_consumer_framework_web_504af020f2184.pdf
- **South Australian Health and Medical Research Institute (SAHMRI) Framework**
https://www.sahmri.org/m/downloads/20140606_Health_Consumers_in_Research_Report_FINAL.pdf
- **Miller et al (2017), Integrating consumer engagement in health and medical research – an Australian framework**
<https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-017-0171-2>
- **INVOLVE (2014): Taking stock of the evidence base for the impact of public involvement in research: An invoNET roundtable discussion, Eastleigh: INVOLVE**
https://www.canceraustralia.gov.au/sites/default/files/publications/national_consumer_framework_web_504af020f2184.pdf
- **SPOR Strategy for Patient-Oriented Research – Patient Engagement Framework**
<https://cihr-irsc.gc.ca/e/48413.html>
- **The RAPPORT Study (2015) Wilson et al: ReseArch with patient involvement: a RealisT evaluation – the RAPPORT study**
<https://pubmed.ncbi.nlm.nih.gov/26378332/>
- **Shippee et al (2013), Framework for Patient Involvement in Research**
<https://pubmed.ncbi.nlm.nih.gov/23731468/>
- **Hamilton et al (2017), An empirically based conceptual framework for fostering meaningful patient engagement in research**
<https://pubmed.ncbi.nlm.nih.gov/28984405/>



There is a growing commitment to Consumer Involvement by Australian Federal, State and Territory governments and their agencies, leading health and medical research bodies and health consumer organisations.

- **AHRA CCI Statement**
<https://ahra.org.au/wp-content/uploads/2021/02/AHRA-CHF-Position-Statement-Final.pdf>
- **NHMRC The Statement on Consumer and Community Involvement in Health and Medical Research (2016)**
<https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research>
- **NHMRC CCI Resources Toolkit**
<https://www.nhmrc.gov.au/about-us/consumer-and-community-engagement>
- **NHMRC CCI Guidelines for Guidelines**
https://www.nhmrc.gov.au/guidelinesforguidelines/plan/consumer-involvement#toc__492
- **South Australian Health and Medical Research Institute (SAHMRI) Value Statement**
<https://healthtranslationsa.org.au/wp-content/uploads/2020/11/The-value-of-CCI-report-v2.pdf>
- **Health Consumers' Council**
<https://www.hconc.org.au/what-we-do/policy-development/position-statements/#research>

“The key ingredients for implementing Consumer and Community Involvement are senior level champions, funding for dedicated roles, resources and training, and staying on message that ‘consumers add value to research’.”

Anne McKenzie AM
Manager, Community Engagement,
Telethon Kids Institute



As awareness of CCI grows, government, corporate and community organisations locally, nationally and internationally are advancing CCI. Below is a selection of organisations that continue to champion CCI and are, for the purposes of this Handbook, considered among the world leaders. This selection is a valuable resource for those seeking to increase their understanding of CCI.

- **Australian Clinical Trials Alliance (ACTA)**
<https://clinicaltrialsalliance.org.au/resource/consumer-involvement-toolkit/>
- **Cancer Australia**
<https://www.canceraustralia.gov.au/about-us/who-we-work/consumer-engagement>
- **Consumer and Community Involvement Program (CCI Program)**
<https://cciprogram.org/>
- **Meeting for Minds**
<https://meetingforminds.com/>
- **National Health and Medical Research Council (NHMRC)**
<https://www.nhmrc.gov.au/about-us/consumer-and-community-engagement>
- **South Australian Health and Medical Research Institute (SAHMRI)**
<https://www.sahmri.org/consumer-community-engagement/>
- **Telethon Kids Institute (Western Australia)**
<https://www.telethonkids.org.au/globalassets/media/images/pagessections/research/help-shape-our-research/the-green-book-mar08.pdf>
https://www.telethonkids.org.au/globalassets/media/images/pagessections/research/help-shape-our-research/purple_planning_book_271015.pdf
- **Victorian Comprehensive Cancer Centre**
<https://www.viccompcancerctr.org/about-vccc/consumer-engagement/>
- **INVOLVE – United Kingdom**
<https://www.involve.org.uk/>
- **Patient-Centred Outcomes Research Institute (PCORI) – United States**
<https://www.pcori.org/>
- **Strategy for Patient-Oriented Research (SPOR) Canada**
<https://cihr-irsc.gc.ca/e/48413.html>

Full List of Resources

		ORGANISATIONS	RESEARCHERS	CONSUMERS	FUNDERS	
Resource 1:	Overview of CCI	●	●	●	●	Pg 17
Resource 2:	Types of Consumer Involvement	●	●	●	●	Pg 18
Resource 3:	Organisations Leading Consumer Involvement	●		●		Pg 20
Resource 4:	CCI Policy for Organisations	●				Pg 21
Resource 5:	Policy Checklist	●	●			Pg 22
Resource 6:	Communication to Stakeholders	●			●	Pg 23
Resource 7:	Researchers: Why Involve Consumers in Research		●			Pg 24
Resource 8:	Consumers: Why Get Involved in Research			●		Pg 25
Resource 9:	Involving Consumers in Funder Activities				●	Pg 26
Resource 10:	CCI Policy for Funders				●	Pg 27
Resource 11:	Creating a CCI Culture	●	●		●	Pg 29
Resource 12:	Involvement Costs and Considerations	●	●		●	Pg 30
Resource 13:	CCI Coordinator Role	●			●	Pg 31
Resource 14:	Recruiting Consumers	●	●		●	Pg 32
Resource 15:	Interviewing Potential Consumers	●	●		●	Pg 33
Resource 16:	Setting up a Consumer Register	●	●		●	Pg 34
Resource 17:	Request for Expression of Interest	●	●		●	Pg 35
Resource 18:	The Role of the Mentor	●	●		●	Pg 36
Resource 19:	Consumer: Approaching an Organisation			●		Pg 37
Resource 20:	Consumer: Assessing the Opportunity			●		Pg 38
Resource 21:	Committee Terms of Reference	●	●	●	●	Pg 40
Resource 22:	The Involvement Agreement	●	●	●	●	Pg 41
Resource 23:	Induction and Orientation	●	●		●	Pg 42
Resource 24:	Remuneration Claim Form	●	●	●	●	Pg 43
Resource 25:	Managing for Success	●	●	●	●	Pg 44
Resource 26:	Managing for Success	●	●	●	●	Pg 45
Resource 27:	Evaluating the Involvement	●	●	●	●	Pg 47
Resource 28:	Reflecting on the Involvement	●	●	●	●	Pg 48
Resource 29:	Concluding the Involvement – Planned	●	●	●	●	Pg 50
Resource 30:	Concluding the Involvement – Unplanned	●	●	●	●	Pg 51

We hope this Handbook becomes a valuable tool as you work to embed CCI in your research.

The WAHTN is proud to have led this project on behalf of AHRA.



We are indebted to our AHRA colleagues for their important contribution to this Handbook.



We sincerely thank the organisations, researchers and consumers who have patiently and enthusiastically road-tested many versions of this Handbook and provided valuable input and advice. You made this Handbook possible.



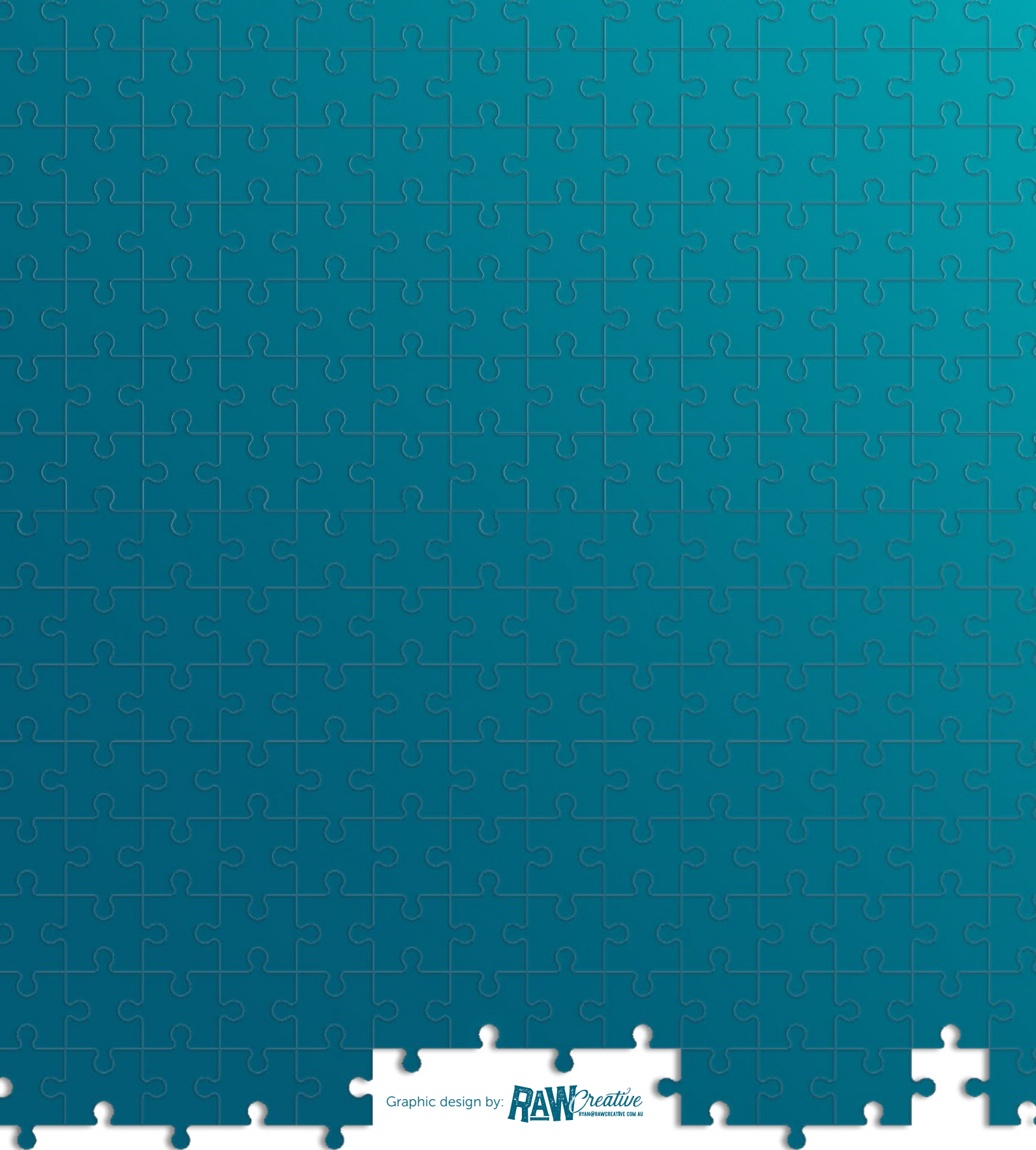
Consumers Health Forum of Australia is a valued partner in this project.

We acknowledge the work of the Project Team members who have created this remarkable resource.

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