



# Supporting Ethics Committees to Amplify Consumer and Community Involvement in Health and Medical Research, HREC Conference 30 November 2023

Brian Dalton, Sydney Local Health District (SLHD) Ethics Committee Consumer (Lay Person) representative member; Consumer member of [Consumer Voices in Clinical Trials NSW \(ConVICTioN\)](#)

Carrie Hayter, Consumer Engagement Manager, Health and Medical Research, Health Consumers NSW

# Why this presentation?

---

- What should an ethics committee be looking for to demonstrate effective Consumer and Community Involvement in Health and Medical Research?
- What infrastructure is needed to support ethics committees in supporting good Consumer and Community Involvement in Health and Medical Research?
- What would we like to see in the future?

# Involving consumers in health research

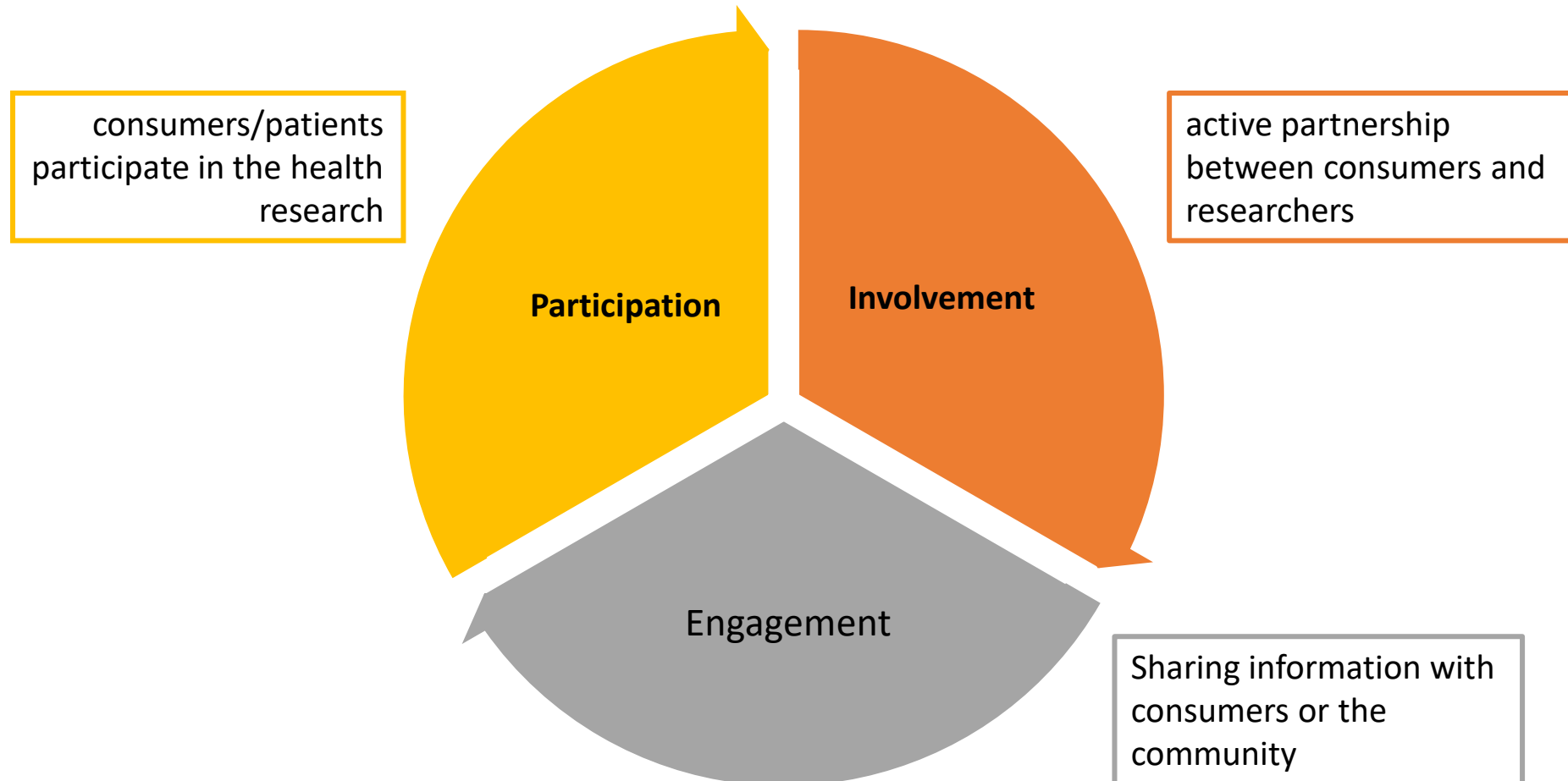
- Capacity building for consumers and researchers
  - Training for researchers and consumers in consumer and community involvement
  - Consumers in Research – online community for consumers interested in research
- Strategic partnership with Research Organisations (eg Sydney Health Partners, UNSW Health and Medicine, The University of Sydney – Faculty of Health and Medicine)
- Consumer awareness of clinical trials  
[www.consumervoices-clinicaltrials.com.au](http://www.consumervoices-clinicaltrials.com.au)

# Consumer & Community Involvement (CCI) in research Governance and Leadership



1. ***‘Nothing about us without us’*** - as beneficiaries of advances in health care, consumers and researchers have an interest in promoting the translation of research into improved policy and practice
2. The form (backgrounds, interests, perspectives) and degree of CCI must be appropriate to the research activity
3. Demonstrating how consumers and the community are involved in health research is being demanded by:
  - Consumers
  - Institutions
  - Ethics committees
  - Funders

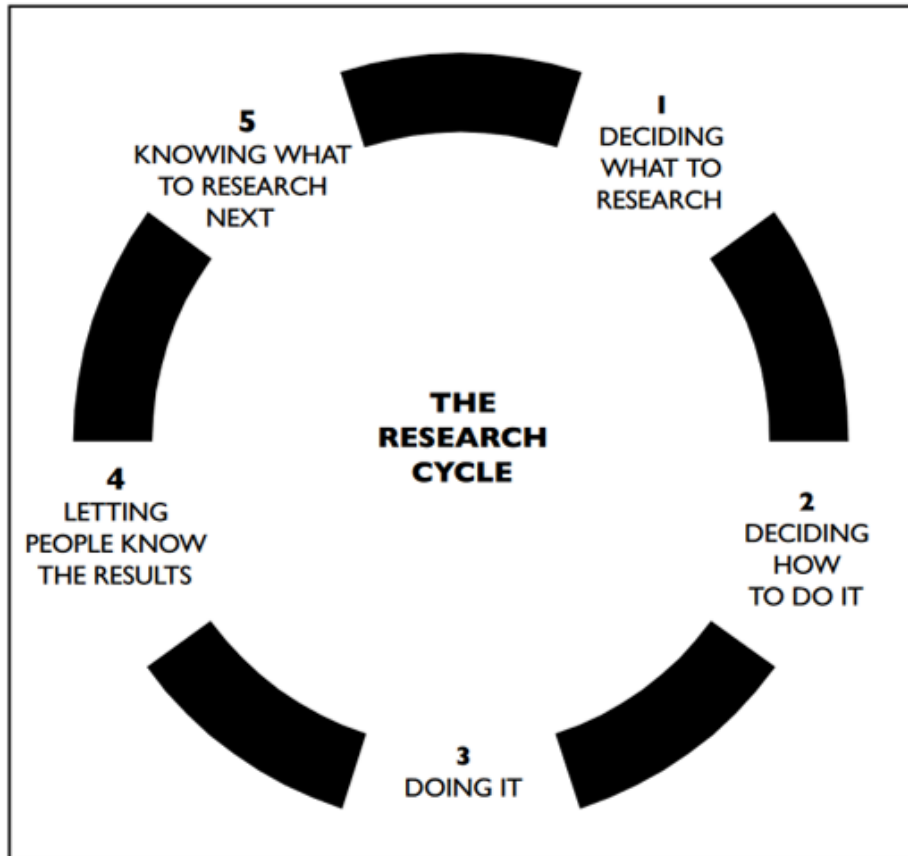
# Participation, Involvement and Engagement (PIE) in health research



# CCI in research

## Governance and Capacity building

What to look for – *'demonstrative' evidence that CCI is working alongside at various levels of research, stages of the research cycle and in the institutions in which research is conducted*



<b>Managerial</b>	✓ part of an organisation's Research Management Group
<b>Preparatory</b>	✓ Oversight - Steering Committee ✓ Responsive – eg: development of Grant proposal, Protocol)
<b>Execution</b>	✓ Oversight – data monitoring committee; patient research partners group ✓ Study design and procedures ✓ Participant recruitment
<b>Translational</b>	✓ Publication/dissemination ✓ Implementation (eg: developing guidelines) ✓ Evaluation

# CCI in research

## Governance and Capacity building - what to look for

Not tokenistic	A clear Vision and Purpose, Terms of Reference actively supporting CCI
HREA, Study Protocol listing of researchers, consumers and consumer researchers engaged in the study	<ol style="list-style-type: none"><li>1. Inclusion of a statement in the Protocol (or submission of a CEP template with an application), detailing how consumers will be involved in the design, delivery and measurement of the clinical trial</li><li>2. Preliminary research stages (eg: co-planning, co-designing)</li><li>3. Analysing findings</li><li>4. Helping design and deliver further involvement/engagement activities</li><li>5. There is a diversity of CCI</li></ol>
Review for consumer-centred Good Clinical Practices (GCPs) to be evidenced by:	<ol style="list-style-type: none"><li>1. Ethical probity - Clinical and benefit outcomes (patient-centred)<ul style="list-style-type: none"><li>• aligned to the needs of the people it is trying to help;</li><li>• beneficial in terms of delivering meaningful outcomes for patients;</li><li>• conducted in a way that is sensitive to participants' needs.</li></ul></li><li>2. Participant recruitment</li><li>3. Participant participation<ul style="list-style-type: none"><li>• PISCF (information transparency, comprehensible by the average participant)</li><li>• Risks and burdens (safe environments)</li><li>• Equity and vulnerable/priority cohorts</li></ul></li></ol>

# CCI in research

## *Support Infrastructure and Leadership*

### For example:

#### A monthly SLHD Ethics Committee standing agenda item

- ☑ As per Standard 2 of The National Clinical Trials Governance Framework, investigators are asked to provide an annual update with their annual progress report (milestone) on the ongoing involvement of consumers in the planning, design, delivery, measurement and evaluation of the trial.
- ☑ The Clinical Trial Milestones (Annual and Quarterly) will be reviewed by the Clinical Trials Executive Officer to ensure consumer engagement involvement/action plans have been submitted.
- ☑ All designated members review + CTSc Executive Officer

	REGIS REFERENCE NUMBER	STUDY STATUS	RPAH SSA SUBMITTED & AUTHORISED?	CONSUMER ENGAGEMENT UPDATE PROVIDED?	Ethics Expiry Date
1	2020/ETH03132	Complete	Yes	N/A	11/03/2026
2	2021/ETH00068	In progress	Yes	N/A	23/04/2026
3	2021/ETH11289	In progress	Pending	Required	14/10/2026
4	2022/ETH00969	In progress	Yes	N/A	07/07/2032
5	2019/ETH00624	Not yet commenced	Yes	N/A	05/06/2024
6	2019/ETH00624	Not yet commenced	Yes	N/A	05/06/2024
7	2019/ETH00624	Not yet commenced	Yes	N/A	05/06/2024

<https://www.hcnsw.org.au>



# CCI in research

## *Support Infrastructure and Leadership*



### **For example the Sydney Local Health District (SLHD)**

now requires the inclusion of a statement in the Protocol (or submission of a CEP template with an application), detailing how consumers will be involved in the design, delivery and measurement of the clinical trial.

#### Consumer Engagement Plan (CEP) - Ethics Specific

Study and status:

Plan(s) to involve consumers – ‘consumer consultation was sought when designing this trial and was part of the successful MRFF and NSW Health grant application processes. Prospectively, the ‘XYZ’ Institute has a Consumer and Community Group within the Cardiovascular Division who will be providing ongoing consumer input as per the below timelines’

<b>Consumer Engagement</b>	<b>Timeline</b>
Co-design of trial and trial documents	Completed
Review of study findings	Following study completion and analysis
Dissemination of trial findings across consumer and stakeholder networks	Following study publication in peer-reviewed journal
Co-design of larger outcomes trial	Following completion of pilot trial and prior to application for funding of larger outcomes trial

# CCI in research - support infrastructure – capacity building

Institution/Organisation	Resource/ Support
NHMRC	Consumer Involvement Guidelines
Monash Partners	<ul style="list-style-type: none"> <li>• Consumer and Community Involvement Tip Sheets for online platforms</li> <li>• Self-paced online education and training modules and lunchtime online seminar series</li> </ul>
Latrobe University	Consumer Participation in Research
Sydney Health Partners (SHP)	Consumer and Community Involvement Framework, Principles
Australian clinical Trials Alliance (ACTA)	<ul style="list-style-type: none"> <li>• Consumer Involvement and Engagement Toolkit</li> <li>• How to involve CALD populations in research</li> </ul>
West Australia Health Translation Network	CCI handbook <a href="https://wahtn.org/platforms/consumer-and-community-involvement/cci-handbook/">https://wahtn.org/platforms/consumer-and-community-involvement/cci-handbook/</a>
Health Consumers NSW	Introduction to consumer involvement in health research Remuneration and reimbursement guidelines for consumers Online community for consumers in research
Health Issues Centre	Training on consumer engagement in research for consumers and for researchers
Melbourne Academic Centre for Health and Health Issues Centre	Engaging with Culturally and Linguistically Diverse Communities for Medical Research

# Consumer and Community Involvement in research

*In conclusion, the benefits can be specific to consumers, researchers or both*

Aligns the two movements that have influenced healthcare in recent decades – patient and family-centred care and evidence-based practice

## Fostering excellence and integrity

- ✓ garnering ongoing public support, confidence, trust and funding
- ✓ improving ethical standards by seeing issues that are not immediately obvious to researchers
- ✓ greater diversity within the research team

## Improving the experience

- ✓ places the interests of research participants first (protecting their rights, dignity and welfare)
- ✓ alerted to issues in the research aim, design, recruitment and retention strategy, outcome measures, consent process and ethics
- ✓ input into study assessment tools, creating more user-friendly and accessible versions

## Fostering quality and relevance

- ✓ hearing the perspective of those with the lived experience of the health condition being researched, or their carer
- ✓ ensuring that the research purpose and outcomes are grounded in the real-life experiences of consumers
- ✓ Increasing the potential to positively affect community ownership of research findings, translation of those findings (e.g. into practical solutions) and community benefits

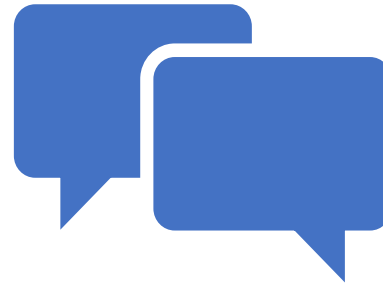
# What we want to see in the future?



**What do Ethics Committees need to foster effective consumer and community involvement in their feedback to researchers?**



**Who should fund this?**



**How do we get consistent feedback across Ethics Committees in Australia?**



**How can consumers and the community be partners in the development of resources and tools?**

# Thank you – Get in touch

---

Carrie Hayter

Consumer Engagement Manager, Health and Medical  
Research, Health Consumers NSW

[chayter@hcnsw.org.au](mailto:chayter@hcnsw.org.au)

