

# Review of the 2016 Statement on Consumer and Community Involvement in Health and Medical Research

## ACTA's consultation submission

Submission date: 15 June 2024

### INTRODUCTION

In March 2024, the NHMRC launched a public consultation focussed on the [Review of the 2016 Statement on Consumer and Community Involvement in Health and Medical Research](#).

The following responses to the consultation guiding questions were submitted by ACTA via the online consultation portal on 15 June 2024.

ACTA thanks the NHMRC for the opportunity to respond to this public consultation.

### ACTA'S RESPONSE TO THE CONSULTATION GUIDING QUESTIONS

#### **The current Statement and importance of consumer and community involvement in research**

##### **What parts of the current Statement have or have not worked well?**

Worked well:

- Clear structure, inclusion of definitions and process of development.
- Inclusion of, and alignment to, international examples and references.
- Appendix 4: Useful resources - however this may need to be located online as inclusion in the Statement means the list is static and not updated.

Has not worked well:

- The Statement implementation was not supported by an implementation plan, and this has led to an ad hoc response to the way it has been implemented and adopted e.g. some have taken up the full intent of the statement and others have seen consumer and community involvement as a 'nice to have'.
- Since the Statement's release there have been multiple guidelines, principles etc developed to support implementing consumer and community involvement. However, this Statement should include adequate information so it can be used as the 'single source of truth'.
- The implementation issues and barriers listed in the current statement are still relevant in 2024, which may mean these issues and barriers need to be explicitly addressed to ensure they can be overcome.
- Language in the Statement is generally passive and places little expectation on researchers, research institutions or research funders.

##### **Why is consumer and community involvement in research valuable?**

- Risk adjusted financial models show that consumer involvement in clinical trials adds considerable financial value e.g. \$62 million savings and 2.5 years of acceleration of a pre-phrase 2 product launch. (see doi: 10.1177/2168479017716715)

- Consumer and community involvement in health and medical research adds significant value in many ways including improved patient-centricity and relevance, enhanced recruitment and retention, added real world context to research, and increased study quality.
- For Australia to be consistent with good practice initiatives in other countries like the UK and Canada, consumer and community involvement should be a requirement for all research that is funded with taxpayer or public money.
- There are large groups of underrepresented people in Australia who do not currently have equitable access to health services and opportunities to contribute to research especially clinical trials e.g. First Nations people, CALD communities, people living with disability, LGBTQIA+, people in rural and remote areas. It will only be by involving diverse consumers and community members in research and clinical trials, that researchers can understand their specific needs and barriers, and that we will change this inequity in access to trials and the outcomes of research.

### **Why does consumer and community involvement in research matter to you?**

As the peak body for the investigator-initiated clinical trials sector, which is often publicly and philanthropically funded, ACTA have a responsibility to maximise the benefit of the research conducted by our members to all Australians. Consumer and community involvement is important to make sure we are researching what matters, researching in a way that is doable, communicated well and respectful to those participating, and retains community confidence in research. For this reason, ACTA is committed to advocacy, support, and inclusion of consumers as partners in clinical trial activities.

ACTA advocate that health and medical research can only be truly efficient and effective if it includes involvement from diverse consumers and community members with relevant lived experience.

### **Value Statement**

#### **What overarching values are essential to include in the value statement of the revised Consumer Statement, and why?**

In addition to the values in the current statement, the following could further enhance the statement:

- Equitable access
- Respect
- Trust
- Collaboration
- Open communication
- Transparency

#### **The values that underpin the 2016 Statement are ‘shared understanding, respect and commitment.’ How might this be strengthened and improved in the revised Consumer Statement?**

While these values effectively underpin the statement, the inclusion of values that demonstrate inclusiveness would be welcome additions.

#### **Should values such as accountability, transparency, collaboration and partnership, equity, diversity and inclusiveness be included in the revised Consumer Statement?**

Yes – these would be valuable additions to the revision of the consumer statement.

### **Better practice principles for consumer and community involvement in research**

#### **What do you regard as the most important principles that should be included in the revised Consumer Statement?**

Existing principles:

- Consumers and community members should be involved at all stages of research: this shows a commitment for embedding representative engagement rather than it being perceived as an ‘add on’ activity.
- Mutually respectful relationships: this shows a commitment to remove power imbalances (real or perceived).
- Diversity and equity: this ensures involvement is reflective of the community.

Additional principles:

- Benefit to consumer and community involvement - a commitment to the outcomes of involvement.
- Action – a commitment to progressing the statement.
- Allyship – a commitment to working together to enhance health outcomes through health and medical research.
- Enthusiasm – a commitment to embrace the opportunities consumer and community involvement brings to health and medical research.
- Responsibility – a commitment to lead and be accountable for consumer and community involvement, and in health and medical research.
- Prioritisation – a commitment to active involvement.

### **Roles and responsibilities**

#### **What roles and responsibilities for consumers and community members should be included in the revised Consumer Statement?**

In addition to the roles and responsibilities for consumers and community members in the current Statement and the Position Paper, the following could be also considered for inclusion:

- **Seek opportunities** to be involved in health and medical research.

#### **What roles and responsibilities for researchers should be included in the revised Consumer Statement?**

In addition to the roles and responsibilities for researchers in the current Statement and the Position Paper, the following could be also considered for inclusion:

- **To value, listen and learn from** the unique perspective and insights of consumers with and community members with lived experience can add to health and medical research.
- **To ensure** diversity of the consumer voice in each research team.
- **To acknowledge** that diversity is integral to research and therefore consumer voices on research teams must also be reflective of this.
- **To treat** consumer and community members as equal and key to the team as other research team members, including openly and transparently communicating at all stages of research.
- **To welcome and support** consumers and community members to share and have a voice in health and medical research. To involve consumers and community members as co-authors in publication of research.
- **To demonstrate** how consumers will be supported (funded) for their contributions e.g. as evidenced through a budget in grant applications.

#### **Should involvement of consumers and community members be an expectation of research?**

- Yes
- No
- Not sure

#### **Provide reasons for your response below.**

There is an imperative for research to reflect and benefit the diversity of the populations it aims to serve. The best way to ensure health and medical research is inclusive, is to involve consumer and community members in its design and conduct. Additionally, due to limited resources, there is a need to minimise waste and focus

on the research that matches the priorities of the community and consumers. Therefore, it is important that consumers and the community are involved in making decisions about what can most effectively benefit the priorities of target populations.

### Is there an ethical imperative to involve consumers and community representatives in research?

- Yes
- No
- Not sure

#### Provide reasons for your response below.

Consumers and community members should be involved in identifying what is important to the community, developing protocols that make it easy to participate, helping develop processes that support participation, ways to disseminate results/outcomes etc.

When considering consumer and community participation in research, the purpose of undertaking health and medical research is to test hypotheses which may compare, trial, or increase knowledge which can ultimately improve health outcomes for consumers and the broader community. This often requires direct consumer input (e.g. through pharmaceuticals or medical device use, providing samples, sharing individual data and inputting into population data). ACTA believes there is an ethical imperative to include consumer and community member input into all health and medical research to ensure this research is conducted **with** the community, not **for** the community.

### What roles and responsibilities for research institutions should be included in the revised Consumer Statement?

In addition to the roles and responsibilities for research institutions in the current Statement and the Position Paper, the following could be also considered for inclusion:

- Undertake routine cultural awareness and diversity/competency training as a required professional development area for all clinical trial staff. This would be underpinned by a learning needs assessment.
- Actively recruit, train, and develop researchers and staff from diverse backgrounds and experiences, with support and pathways for career development and leadership.
- Actively recruit, engage and support consumers and community members from diverse backgrounds with relevant lived experiences.
- Create policies and processes that promote the value of and provide supporting structures for people from diverse backgrounds within their workforce.
- Develop policy, processes, and resources to support consumer and community involvement at a site level.
- Develop policy, processes, and resources to support researchers in consumer and community data collection and evaluation.
- Adequately fund and resource consumers for their contributions.
- Ensure consumer involvement is both funded, or that funds secured for that purpose, are actually acquitted that way.
- Embed consumer and community members within Institute operations e.g. through Board and/or advisory representation.

### What roles and responsibilities for research funders should be included in the revised Consumer Statement?

In addition to the roles and responsibilities for research funders in the current Statement and the Position Paper, the following could be also considered for inclusion:

- Research funders have a responsibility to make consumer and community involvement a mandatory requirement in all research grants.

- Research funders should ensure that all grant documentation includes standardised requirements for consumer and community involvement (e.g. line items within budget templates) and provide adequate guidance and expectation to grant submitters that consumer involvement be budgeted.
- Research funders must ensure that grant funding allocations include provision for all additional costs required to fulfill consumer and community involvement. For example, grant budget guidelines and templates should include a guide for consumer remuneration (e.g. to provide honorariums, travel, out of pocket costs, etc) to ensure there is consistency in payments across all research, institutes and entities.
- Research funders must consider the capacity of consumers to take on unfunded involvement.
- Research funders should demonstrate their commitment to consumer and community involvement by including consumers and community members in the decision making processes around their grant schemes e.g. governance structures, grant scheme design or targeted calls.
- Research funders must ensure that consumers are invited and included on grant reviewing panels, and they are considered equal reviewing partners e.g. equal voting rights.
- Research funders must ensure that when reviewing grant submissions, the consumer involvement scores are included in overall score.

### Should funders of research mandate the involvement of consumer and community representatives in the research they fund?

- Yes
- No
- Not sure

Provide reasons for your response below.

There are currently broad inconsistencies and gaps in how consumers and community members are involved in health and medical research. A funder driven mandate would help to create consistency and provide gravitas to the necessity of consumer and community involvement in health and medical research, as well as the various roles consumers may take on across the research enterprise.

A consumer and community involvement mandate would also bring Australian research in line with good practice initiatives used in other countries like the UK and Canada.

### Implementing the revised Statement

#### How should researchers involve consumers and community representatives in their research?

- **Engage** by sharing information and knowledge about health and medical research with consumers and the community so that they are better informed on why, how, where and by whom research is conducted, and the outcomes of that research. This includes creating a dialogue with consumers and the community to improve research literacy and increase awareness to consider clinical trials as one of the potential options available to them as part of routine care.
- **Involve** consumers and community members in decision-making processes with researchers and research organisations about health research priorities, policy, and practice. This can include (but is not limited to) defining research questions, identifying outcomes of interest, and improving the content and readability of participant information. The aim of better involvement is that research priorities are reflective of the population and may more effectively improve health outcomes.
- **Provide opportunities** for consumer participation where patients or healthy volunteers take part in research including being recruited to take part in a clinical trial, completing a questionnaire or attending a discussion group as part of a research study and/or providing data or tissue that is analysed as part of a research study.
- **Close the loop** at the completion of health and medical research to establish trust and understanding for consumers and community members. This transparency and reciprocity will also enhance future trial design.

- **Educate** consumers and the community on the opportunities and benefits of being involved in health and medical research.
- **Collaborate** with diverse consumers and community members from targeted populations to increase equity and collaboration in trial/study design.

**What issues should be considered once the revised Consumer Statement has been finalised and published?**

- Ensuring there is adequate access to relevant and diverse consumer cohorts.
- Providing remuneration to consumers who provide their time and insights.
- Allocating funding that can be made available to medical institutes and entities that conduct research who require support to establish and implement consumer and community involvement processes.
- Embedding mandatory and consistent consumer engagement requirements within all medical and health research grants.
- Adopting a standardised approach to reporting on consumer engagement within grant deliverables reporting.
- Providing practical advice and tools to researchers on how to best engage and involve consumers.
- Reviewing research funder clinical trial guidance to ensure the inclusion of different consumer and community groups in trial selection criteria and study populations, as well as the inclusion of a requirement to report on the group's participation.
- Reporting on how Australian health and medical research is positively impacted through the statement.
- Further embedding the Statement into other processes and documentation will demonstrate that the Statement isn't a standalone document.
- Provide guidance on how researchers can work with consumers as co-authors of publications (e.g. <https://doi.org/10.1002/leap.1607>)