Review of the 2016 Statement on Consumer and Community Involvement in Health and Medical Research – Position Paper Questions

We are encouraging all interested stakeholders to provide a written submission to the questions in the NHMRC Consumer Statement Review Position Paper via NHMRC's Consultation Hub. These questions will also be discussed in an open forum at Australia-wide workshops in the first half of 2024.

You may enter your responses directly using the online survey. If you provide an email address, you can save your progress and return to the survey as many times as you wish while it is open.

This document has been developed for individuals and organisations who would prefer to prepare their responses offline, for entering on NHMRC's Consultation Hub once complete. It contains the discussion questions in the order that they appear in the online survey.

Please note that none of the questions below are mandatory, and that there is no word or character limit for each question in the online survey. You are welcome to provide a response to as many or as few questions as you wish. You will also be asked some questions about you or your organisation when you complete the online survey.

Please ensure that you have read the Position Paper (available for download on the Overview page of the survey) prior to answering the questions.

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

The current (2016) statement is available for download from NHMRC's website at: https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research

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

The current statement contains all the elements required for an overarching statement.

However, there are several elements that could be improved:

- Detail of the statement reads as consumer participation being a value add, an optional extra, rather than an integral part of the research process.
- The statement also reads as having researchers as the target audience. We encourage the NHMRC to consider the perspectives of both consumers and researchers in redrafting the statement.
- Consider changing the language from 'consumer' to 'lived experience'. Many people in our community do not like to be referred to as 'patients' but 'person who lives with ME/CFS'.
- Provide more practical examples of different types of involvement from consumers and the community in research, highlighting that consumers may often require accommodations to participate. For example, people with ME/CFS who are the most

unwell and those who will benefit the most from research findings, are also those who find it the most difficult to participate due to the limitations of the disease.

- Greater promotion of the statement and the ability for organisations like ours to easily share this statement. This would also be assisted by having an accessible version suitable for people with cognitive and energy limitations, as many people with ME/CFS do, as well as CALD groups and people with vision impairments and other types of disability.

- ○ Why is consumer and community involvement in research valuable?

Addressing unmet need should be the reason for conducting all research. For example, for people with ME/CFS, research has too often posed risk and harm to patients due to poorly designed studies that either use inappropriate testing, or don’t inform patients of potential harm.

In addition, with Long COVID, we are seeing research being unnecessarily repeated and the same mistakes being made.

Consumer and community involvement should:

- result in better-targeted research, addressing known problems and providing translatable outcomes. Consumers can assist greatly in disseminating these outcomes, using their networks and ensuring findings are presented in accessible language and formats.
- help to keep researchers accountable.
- aid funders to know which research to fund; on relevant research that will benefit patients.

- ○ Why does consumer and community involvement in research matter to you?

Consumer and community involvement matters to Emerge Australia because research is pivotal to our understanding and representation of our community and our ability to advocate for them.

Our organisation runs a research registry and biobank that was established for people with ME/CFS. These individuals contribute valuable information about their illness, complimenting the research conducted on their blood donations. This research has connected us with other organisations, enabled us to promote research into ME/CFS and provide practical assistance to other researchers to conduct their studies.

This gives our community visibility and action they have not had before in Australian research. This is important because it provides researchers with unique insights into ME/CFS, hopefully leading to more focused research, that directly benefits those most affected.

Value Statement

A value statement is important as it is a brief, high-level statement that underpins and acknowledges the spirit and purpose of consumer and community involvement in the research cycle. The value statement will help to embed the aspirations of the principles into better practice.

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

The following values should be included:

Safety, accountability, transparency, collaboration and partnership, equity, diversity and inclusiveness.

Including these values acts to set a more comprehensive tone about research activities in Australia.

People with ME/CFS would specifically value "safety" as they have, in the past, participated in research that exacerbated symptoms, which for some people was experienced permanently. This relates to the energy limiting nature of the disease, and the potential harms caused if these energy limits are exceeded, either intentionally or unintentionally.

- 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?

As above.

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

Yes. As above.

Better practice principles for consumer and community involvement in research

The Position Paper provides some examples of broad principles that could be included in the revised Statement. You are welcome to provide comments on these examples, or on any other principles you would like to see included.

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

All of the proposed principles are welcome. The principles that are most important to include in the revised consumer statement are those that highlight the importance of consumer participation from a position of equity with researchers.

A combination of the proposed principles to include in the revised Statement may read as:

- Respect for consumers and community members with lived experience and community expertise is demonstrated by being in partnership with researchers, involved at all stages of research and representing broad diversity and equity.

- Honesty in the development, undertaking and reporting of research, including presenting information truthfully and accurately in proposing, conducting and reporting research.

Following these principles, the statement should include specific examples of how consumers are involved at all stages of the research, what diversity can include, and equity means in practice.

For example, for someone with ME/CFS, diversity could mean representation of the spectrum of disease severity, where they reside (city/rural/regional/state) or any other number of combinations. This diversity must be representative and relevant for it to be most useful and equitable in the research process. See the next answer for further discussion.

Roles and responsibilities

The Consumer Statement Review Position Paper provides some examples of roles and responsibilities **of consumers and community members, researchers, research institutions and research funders** that could be included in the revised Statement. You are welcome to provide comments on these examples, or on any other roles and responsibilities you would like to see included.

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

In this section, the word "best" should be replaced for a word that has more meaning and sensitivity to the purpose of consumer participation. "Most representative" would be more suitable, as it suggests there are multiple factors which should influence who is most suited to be involved – including factors discussed in the previous question such as diversity and equity.

Further, the consumer should be thought of for their unique skills, knowledge and lived experience. As a whole person, not just a representative of their disease, for example, means they are more highly valued. It should also mean that the consumer can be thought of as able to fill a variety of roles.

Consumer organisations should also be recognised and should be funded to be active partners in the research process. As a consumer organisation, we can provide the perspective of a larger consumer cohort and represent their interests. We are also able to connect researchers with a diverse range of consumers in our community.

At Emerge Australia, we are also experienced in conducting our own research. Including consumer organisations would more accurately account for the range of organisations which conduct health and medical research.

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

There should be a recognition of the importance of trauma and risk informed approaches in working with consumers. These are ongoing issues for people with energy limiting conditions like ME/CFS. Many members of our community have experienced trauma because of interactions with health services and engaging with health research risks retraumatising consumers.

In addition, for people with energy limiting conditions, research tasks that involve energy expenditure for study participants, whether this is a deliberate part of the research or consequence of participating, carries the risk of symptom exacerbation for consumers living with ME/CFS.

Although researchers have a responsibility to inform participants of risk through the ethics process, this has not always resulted in a true reflection of the risk of involvement for people with energy limiting conditions. By involving consumers in the early stages of research process should prevent studies like these from causing harm, and research participants be informed of potential harms.

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

  Yes ☒
  No ☐
  Not sure ☐

  Provide reasons for your response below.

Yes. As the ultimate beneficiaries, consumers and the community have a right to be integral and active partners in all health and medical research. Consumer and community involvement means:

- Health research is improved through more relevant research, catering to the needs of participants.
- Stronger imperative to focus on health outcomes, with more likelihood of these outcomes being disseminated through the community to those who are most likely to benefit.

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

  Yes ☒
  No ☐
  Not sure ☐

  Provide reasons for your response below.

Yes. Consumers and the community have a right to be involved in research for and about them. They also have the right to be involved in all stages of the research process, to ensure the research is relevant, safe and new.

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

It is the responsibility of research institutions to ensure that consumer participants are adequately supported in their role. This may mean investing in developing skills, networks and/or accessibility strategies to encourage and support consumer participation.

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

It should be a responsibility of research funders to require consumer participation in all funded research projects. To further ensure consumer participation is integrated throughout all research phases, applications should be ranked based on consumer involvement.

- 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.

Yes. However, mandating consumer and community representatives in research must be supported with practical measures to ensure researchers fully and appropriately involve these representatives.

NHMRC may consider:

- Funding online tutorials for consumers and researchers on the NHMRC grants process.
- Developing a plan to measure what good Consumer and Community Involvement looks like from a consumer perspective in NHMRC grants.
- An evaluation process as part of grant reporting, where community participants provide an account of their expected, and actual, involvement in the research. This would assist with monitoring effectiveness and identify where further assistance can be provided.

Implementing the revised Statement

The revised Statement is intended to be a high-level, overarching document that does not focus on issues related to implementation of consumer and community involvement in health and medical research. However, we acknowledge that you may like to share your views on how the revised Statement may be implemented. Responses to the questions on this page may be used to develop implementation guidance once the revised Statement is published.

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

Researchers should work in partnership with consumer organisations like Emerge Australia to support the involvement of consumers and the community at all stages of health and medical research.

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

The involvement of consumers and the community in health and medical research requires the funding of infrastructure to support the **capability** and **capacity** of consumers to be involved in health and medical research. Consumer organisations approached to be research partners for NHMRC grants are often asked to provide in-kind support for research grants which often is not financially possible or sustainable. Consumer organisations should be funded to be research partners in NHMRC grant applications.

Consumer organisations need additional funding to build a pool of consumers trained in understanding health research. NHRMC should fund consumer organisations to build and develop infrastructure to support the capacity of consumers to be involved in research.