



ACCESSCR

Submission to the
'NHMRC Review of the
National Statement on
Consumer & Community
Involvement in Health and
Medical Research'
June 2024

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About This Document

The document collates AccessCR's response on the 16th June 2024 to the NHMRC Review of the 2016 Statement on Consumer and Community Involvement in Health and Medical Research.

More information on the review is available online at: <https://www.nhmrc.gov.au/about-us/consumer-and-community-involvement/about-review> and on the NHMR Consultation Hub: <https://consultations.nhmrc.gov.au/research-partnerships/review-of-the-statement-on-consumer-and-community/>

Background to AccessCR

As background and context for the submission, AccessCR is a social enterprise providing services to the research sector supporting clinical trials and consumer engagement and involvement in research. The goods and services we provide fund our advocacy and support activities for those we call CCRew - the Community and Consumer Research Workforce. We define CCRew as the individuals (and their carers/families) taking part in and contributing their lived experience to health and medical research, particularly clinical trials.

Learn more about us at the [AccessCR](#) and [CCReW](#) websites, and help support our work with a purchase from our [online shop](#).

Consultation Questions

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

Worked well:

- That there is a Statement that can be referred to as an expectation of research.
- There is a case made for the benefits of involving consumers, and some guidance on making it happen in practice

Has not worked well:

- The presentation is wordy and not particularly accessible. A future Statement should align its language, presentation and accessibility to the intended audience.

- It is not completely clear whom the audience of the Statement is. Is it for anyone conducting research (ie research sector), anyone with an interest in research (consumers interested in contributing to research), local or international funders of research in Australia or the community at large to provide a vision for the expectations of researchers to involve consumers.
- There are stakeholders with a role in research or in supporting consumers that have not been mentioned or assigned roles and responsibilities, for example Human Research Ethics Committees, health consumer organisations, and commercial sponsors of research.
- There is confusion in the document in the use of words 'participation' and 'involvement'. A future statement should be very clear on the meaning of the word participation, engagement and involvement, in order to avoid confusion between the role of participation in research (an activity an individual will typically consent to and provide data/samples to) verse involvement (where there is an element of intellectual or experiential input, information exchange, a contribution to decision-making, teamwork and collaboration). Consideration could be made to aligning the definitions with those in the ACTA toolkit (<https://involvementtoolkit.clinicaltrialsalliance.org.au/toolkit/understanding/about-involvement-and-engagement/>), but also being mindful to how those words are then used throughout the Statement.
- As a Statement, it is neither well-known nor mandatory in nature, and as such, can be ignored. If the intention is to make sure there is consumer involvement throughout the governance and lifecycle of research, then it needs to be better integrated into other documents that guide the conduct of research in Australia, such as the Australian Code for the Responsible Conduct of Research, the National Statement on Ethical Conduct in Human Research, any grant funding rules as well as related policy documents (current and evolving).
- If the evidence demonstrates consumer involvement is beneficial, then the Statement must be supported by the provision of training, infrastructure and funding (for both the researcher and consumer workforces) to support the change in ways of working, as well as efficient and sustainable consumer involvement in research. The lack of committed, long term investment in consumer involvement to date has kept consumer involvement as an optional, nice to have, cottage industry, devoid of diversity in involvement, available only to those that can afford to do it/be involved, and not reaching its full potential to minimise research (and funding) waste.
- It is not necessarily clear to whom the Statement applies – all research or just publicly funded research. There are stakeholders such as industry, health services and human research ethics committees that are not specifically identified in the Statement but whom have a role and hence potentially responsibilities with respect to consumer involvement in research. Consideration could be given to changing 'research institutes' to 'organisations conducting research' as a way of broadening the reach of the Statement.

Why is consumer and community involvement in research valuable?

Consumer and community involvement in research fills the gap in knowledge between what is learned theoretically, or observed through clinical practice, and the lived experience. It is valuable for improving understanding of health (good and bad), prioritising what matters to those impacted, how health “care” is accessed and fits into the logistics of life, the unmet needs and areas for improvement. It helps focus research to be more relevant, achievable, and translatable. It makes research more accessible to the general public and helps identify inequities that may need addressing.

The financial business case for involving consumers in therapeutic product development has been made (<https://journals.sagepub.com/doi/full/10.1177/2168479017716715>). By extension, publicly funded research would similarly experience efficiency gains from consumer involvement through improved prioritisation, improved recruitment and retention, reduced protocol amendments and improved dissemination, hence reducing research waste.

Involving consumers will help maintain Australia’s standing and competitiveness in an international landscape increasingly recognising and mandating consumer involvement in research (US, Canada, Europe, WHO). In May, the World Health Assembly meeting (WHA77) adopted the resolution (voted for positively by Australia) “Social participation for universal health coverage, health and well-being”, sending a very clear message of the importance of involving people in decision-making processes across all levels of the health system and policy (https://apps.who.int/gb/ebwha/pdf_files/WHA77/A77_ACONF3-en.pdf). Locally, MTPConnect’s newly launched report on Australia’s clinical trials sector identified improving patient engagement (consumer involvement) as an opportunity to embrace to further improve the competitiveness of sector (https://www.mtpconnect.org.au/images/MTPConnect_2024_AustraliasClinicalTrialsSectorReport.pdf).

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

The research sector has limited funding and resources, and so it has to work efficiently to ensure research is being done to address what matters to the community, in a way that is respectful to the communities it aims to serve (including those that participate in the research). AccessCR is particularly committed to improving the efficiency of clinical research, and equitable access to participate in and benefit from the outcomes of clinical trials. We do not believe any of that can be achieved effectively without all stakeholder groups being part of the process.

Health consumers are an important stakeholder of research, and as such, deserved to be involved in its governance and all aspects of prioritising, designing, reviewing, conducting, disseminating and translating its outputs, as much as any other stakeholder group. Their lived experience complements the scientific, ethical and operational expertise brought by other stakeholders. Consumer involvement ensures the relevance of research, the accessibility and inclusiveness of it. It can help identify areas of burden of participation that should be considered or supported. Involving appropriate consumers can lead to greater awareness and acceptability of research, and the social license of the public to continue research.

In our view, there is significant risk of inefficiency, irrelevant research, increased waste, and continued inequities in access to and the benefits from research, if we don't include diverse consumers with the appropriate lived experience in all facets of the research process.

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

The following are values we would like to see adopted across both the research and consumer sectors with respect to consumer involvement in research:

Respect: All parties bring their own skills, knowledge and experience to a task, project or committee. It is incumbent on all parties to respect what others bring to the table - to communicate effectively and considerately, to actively listen and consider diverse views and input, to be kind and compassionate, to be open-minded. It also requires active consideration to the power imbalances that may exist around the table, include ensuring consumers are appropriately compensated for the time and expense of being involved.

Honesty & Integrity: The public have to trust in the process and outputs of research. One way to foster that trust is to act with honesty and integrity in the design, review, conduct, and reporting of research. Being honest includes being transparent. Assumptions, biases, agendas and conflicts of interest that have the potential to (or a perception to) influence research must be actively disclosed and managed in order to maintain public trust in and the social license for research.

Diversity: The Australian population is diverse from demographic factors (like age, sex, gender, race, ethnicity) to behavioural and social determinants of health (like location, socio-economic factors, education, language, general and health literacy, healthcare access, etc) and from lifelong to acute, chronic or life-threatening health conditions, rare or common. There is also significant intersectionality between all these dimensions of diversity. Where public funds have been used to support research or the outcomes of research (including medical services and therapeutic goods), there is a responsibility to ensure that all parts of the community can understand how applicable that research is to them. Research must reflect the diversity in/of the community and to meaningfully involve groups not historically well represented in research.

Equity and Inclusion: Research must take into consideration the needs of different individuals and the diversity of the community, to ensure there is equity of access for individuals and communities to information, opportunities to contribute to or participate in research, and hence to improve their own lives. Being inclusive requires intention – to reflect on one's own biases, to actively engage to understand barriers to inclusion, to commit to addressing barriers when observed/identified wherever possible, and to be open about limitations so as to maintain trust.

Accountability: Research funded by the public must be accountable to the public for delivering on what matters to the public, and what is promised in funding applications. Involving the public in the prioritisation, design, funding, conduct, and reporting of research, will improve the accountability of research to the public.

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?

We do not support inclusion of the word commitment, as this is a behaviour that underpins action, rather than a value. Commitment in itself does not result in consumer and community involvement in research. Commitment needs to be backed up with clear goals, effort, resourcing, processes and accountability. All stakeholder groups, including consumers, have a responsibility to ensure consumer involvement strengthens, rather than add unnecessary confusion, complexity or burden to the research process and outcomes.

The values could be strengthened by linking them to specific principles, behaviours, and example activities, as exists in the UK’s Involve/HNS NIHR Public involvement in research: values and principles framework (<https://www.invo.org.uk/wp-content/uploads/2017/08/Values-Principles-framework-Jan2016.pdf>)

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

AccessCR has provided above the list of values it would like to see adopted. In the absence of adopting that list, then we support the inclusion of accountability, transparency, equity, diversity and inclusion as appropriate values. We think collaboration and partnership are more behaviours that are necessary for the development of trusted and productive working relationships (and support inclusion of consumers in research).

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

AccessCR’s would encourage a revision of the Principles to align with the ‘Principles for Consumer Involvement in Research Funded by the Medical Research Future Fund’ (<https://www.health.gov.au/resources/publications/principles-for-consumer-involvement-in-research-funded-by-the-medical-research-future-fund?language=en>), with the proviso that rather than leaving the choice solely with the discretion of researchers (ie ‘as appropriate’), that consumers should be involved in decisions regarding how and when consumer involvement is appropriate based on the task, project and cohort of consumers impacted.

AccessCR acknowledges the community and consumers may interact at different governance levels of research, and at different parts of the lifecycle of research, and in different ways and capacities, per the IAP2 spectrum of involvement modified for research (<https://i2insights.org/2020/01/07/research-modified-iap2-spectrum/>), and Cancer Australia Framework for consumer involvement (Figure 2, <https://www.canceraustralia.gov.au/publications-and-resources/cancer-australia-publications/national-framework-consumer-involvement-cancer-control/>). Any principles must allow for involvement ‘optimal’ to the task/activity, as well as acknowledge the choice consumers and the community have whether or not to engage with research, at what level, and to cease that engagement should they wish to.

There are alternative representations of principles we would also support, that may better drive action toward the process/outcomes we want to achieve. Examples of these include those from:

1. UK NHS Health Research Authority (<https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/>):

- Involve the right people
- Involve enough people
- Involve those people enough
- Describe how it helps.

2. the HCCA Framework for consumer engagement, noting we would substitute the word participation with involvement, for consistency (<https://www.hcca.org.au/publication/consumer-and-community-participation-framework/>):

- The right to participate
- Participation is meaningful
- Participation is transparent
- Participation is supported
- Participation is inclusive

AccessCR does not think it appropriate to include a principal about protecting research participants, as the Statement is about Involvement, rather than Participation in research. As it is already a principle in the Australian Code for Responsible Conduct of Research, it should not need to be duplicated in the Statement.

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

To make the document easier to read, we suggest separating 'roles' and 'responsibilities', as suggested in the response to the following questions.

Roles

In addition to supporting the roles described in point 2 of the consultation paper, we'd like the Statement to acknowledge:

- the variety of roles, forms, and degrees of consumer involvement possible
- that roles should be mutually co-designed and agree between researchers and consumers, fit to the nature of the task and the capabilities/resources of the consumer

Additional potential roles (or responsibilities) could be

- to promote the value of research, and;
- to help build capacity in the consumer workforce, by helping encourage, identify and mentor 'new' consumers for roles in research.

Responsibilities

The responsibilities we highlight below for consumers are equally relevant to the research workforce. We have however included them here as a minimum set of responsibilities for consumers:

- To understand and convey the limits of their experience/skills/knowledge/networks
- To engage only with tasks or committees they either have the skills, knowledge and experience for or are willing and able to be supported to gain.
- To commit to understanding and meeting the expectations of the role they have taken on.
- To openly share their knowledge, skills, experiences and networks as appropriate to the given task or activity
- To respect the knowledge, roles and responsibilities of other team members
- To communicate and contribute collaboratively to add value to the task at hand.
- To be mindful of personal agendas, and conflicts of interest that may be counter to the aims and conduct of the research.
- To seek to mentorship and/or continuously learn about (and comply with) the regulations, guidelines and processes/methods in research as appropriate to the work they are involved in.
- To understand the proprietary, sensitive and/or confidential nature of information they may be exposed to and what can/can't be share.
- To support and promote a role for consumers in research, and act with integrity in all working relationships.

It is AccessCR's view that consumers should be considered just another source of expertise that complements the expertise of others with whom they are working in a multidisciplinary fashion with on committees, in projects, in research or governance activities, etc. They bring their own unique skills, experience and knowledge as consumers to the project/task, but are equally responsible for communicating well, working constructively, and doing what is necessary to meet the (reasonable and communicated) expectations placed on them as any others they are partnering with or contributing to.

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

Roles

These could include:

- Promoting the value of consumer involvement
- Working constructively, inclusively and meaningfully with consumers
- Facilitating connections, infrastructure, support and payment for meaningful consumer involvement
- Providing mentorship and guidance to consumers involved in research.

Responsibilities could include:

- To co-develop and negotiate with consumers their roles and responsibilities for a given research activity
- To help consumers fulfil the expectations through support, training and remuneration
- To partner with consumers equally as with other professional colleagues.
- To continuously develop their knowledge and practices for engaging and involving consumers in their work.
- To actively seek out and work to address the needs, barriers and burdens of consumer partners, in order to improve the diversity of consumer voices contributing to research.
- To create accessible ways of working with consumers they want to involve, include considerations of disability access, interpreters, culturally safe and appropriate environments, tech access and support, peer support, etc.
- To acknowledge consumer partner's contributions when reporting on research.
- To report on consumer involvement in their work (how, what, who, when, how often, etc) and its impact(s) in order to help build capacity and knowledge and best practices in consumer involvement.

In summary, researchers will need to 'make room' in research for meaningful consumer partnership, supported with clear expectations, funding, support and encouragement. This may require additional resourcing and changed ways of working, but should ultimately improve the relevance, efficiency and implementation of research.

Should involvement of consumers and community members be an expectation of research? Yes / No / Not Sure Provide reasons for your response below.

Yes. Based on the benefits to individuals, research and society outlined in the current Statement, AccessCR supports consumer involvement to be an expectation of research. There are numerous resources that can support researchers to get started and extend their involvement with consumers. At the very minimum, where consumers are not involved, there should be a clear justification for it that extends beyond a lack of time, resourcing, funding or knowledge.

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

Yes / No / Not Sure Provide reasons for your response below.

Yes. The United Nations Sustainable Development Goal 3 is to ensure healthy lives and promote well-being at all ages. If health is a basic human right, alongside the right to be involved in decisions about one's own health, then AccessCR advocates that there is an ethical imperative for people to be involved in the development and conduct of research, the outcomes of which may one day have an influence on their health and wellbeing.

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

Role

Research institutes have a role in supporting best practice consumer involvement if they are to enhance the grant and research success of their staff and affiliates. Research institutes, as the houses of research, also have a role in maintaining community trust of research, and involving consumers in their governance processes, and being transparent in their operations, can help achieve that.

Responsibilities

Researchers will more readily involve consumers if research institutes make the processes for researchers and consumers to work together easy. Their commitment needs to extend to investment in:

- Training and/or mentorship of researchers and consumers
- Infrastructure (eg policies, databases, networks, etc)
- Efficient processes (eg recruitment and induction of consumers, reimbursement)
- Centralised advice and support for/connection to local/external communities of practice
- Engagement strategies/opportunities for their local communities

Where a research institution cannot directly provide this support, it should make available avenues and funding for its researchers to source this assistance from elsewhere, in order to maintain the competitiveness of its research workforce and connections with local community.

Research institutes should make clear the expectations of those they support (consumers and researchers), and hold all parties accountable to those expectations, as a condition of accessing their training, infrastructure, support and funding.

It may be helpful to also consider Involve Australia's recommendations for Research Institutes (May 2024 - https://www.australiangenomics.org.au/wp-content/uploads/2021/06/Involve-Australia_Recommendations-for-institutes_May-2024.pdf).

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

Role

Funders set the rules for the research they fund, and as such, have a play a substantial role for driving consumer involvement in research. This includes leading by example and involving consumers in meaningful ways in their own governance structures, policy/procedure development and the design and review of grants and funding decisions.

Responsibilities

All research funding should clearly articulate in their funding programs:

- How, when and where they expect consumers to be involved
- The acceptable rates for reimbursement and compensation for consumers
- The types of consumer activities that can be budgeted for
- How consumer involvement will be reviewed, scored and weighted in the overall assessment of the grant application

Research funders should also provide:

- Full funding appropriate consumer involvement activities researchers have requested budget for. (Part funding will lend itself to more tokenistic activity, inconsistent with a mandate for meaningful involvement). On the flip side, they should not fund projects that have not adequately budgeted for consumer involvement activities.
- Guidance and training for grant review panels on the role and expectations of consumer reviewers and how to review and score applications, especially with respect to consumer involvement.
- Best practice examples from successful grant applications to demonstrate their expectations
- Expectations for and guidance on preparing information in lay language
- Guidance and templates for how consumer involvement should be reported, and hold research to account (with consequences) to following through on their commitments to consumer involvement (unless there is a reasonable justification why it was not possible. (Running out of money, reallocating money to other unfunded activities are not a suitable justification).

For noting, consideration could be given to Involve Australia's recommendations for Research Funders (May 2024 - https://www.australiangenomics.org.au/wp-content/uploads/2021/06/Involve-Australia_Recommendations-for-funders_May-2024.pdf).

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.

If there is an ethical imperative to involve consumers in research that will potentially impact their lives, then it makes sense that funders should mandate consumer involvement in research. There should however be consideration allowed for the stage or nature of the research (eg preclinical vs clinical), resources available, and the desire/needs/capacities of those communities to be involved.

AccessCR notes that consumer partnership takes time, and builds at the speed of trust, which is not necessarily based on grant cycles and timelines. A mechanism needs to be available in the short term to support the establishment of relationships and early engagement, pre grant submissions, if we are truly to work towards best practice of involving consumers early in ideation, prioritisation and development of research ideas, such that research teams can be grant ready and non-tokenistic in their efforts. If a mandate for consumer involvement is made, there needs to be a process for seed funding the time and activities to build relationships, understand needs, and contextualise them for the purposes of preparing suitable grant applications downstream.

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

Researchers and consumers would ideally partner to design and conduct research, inclusively, and relevant to the needs of the community. There is no one-sized fits all approach, not two projects that will be identical, especially given the nature and diversity of teams, and the flavour that adds to a project or committee.

When recruiting for involvement activities, consideration should be given to recruiting diversely, matched to the diversity of the target population for the research. In governance structures, recruitment should take into account the diversity of the community in which the organisation is located/services. Once recruited, organisations/research teams should ask consumers about and aim to support their needs so as they can meet expectations.

Ideally, consideration needs to be given to power differentials, peer support, diversity and capacity building, and therefore including more than one consumer in any activity is good practice.

Communication is key to building trust and maintaining long term relationships. Researchers and consumers need to establish the preferred communication channels, frequency of communication and communication needs.

Researchers must also close the loop on involvement activities by seeking feedback from consumers on their involvement experience, to support continuous improvement, as well as informing consumers of the outcomes of the research activities and their impact as consumers on them.

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

As already mentioned, the Statement will require implementation support to achieve its full potential in shifting culture and practice for consumer involvement.

A shorter Statement will be more readable/accessible. However, AccessCR notes that given there is still a large segment of the researcher community that lack confidence or experience in working with consumers, guidance will still be required. We would discourage the development of more toolkits but would encourage compiling a living library of quality resources, toolkits, templates etc that already exist. The living library approach makes sense given the rapidly evolving practice of consumer engagement and involvement internationally, and it will help avoid further duplication in effort by research institutes, networks and communities of practice in creating their own resource libraries. Consideration will need to be given to resources that suit the various different types of research, from bench to bedside and more.

To demonstrate the commitment to consumer involvement, AccessCR would encourage the NHMRC to involve consumers in helping develop the implementation strategies for the Statement, which will need to include awareness raising about both the Statement and the role of consumers in research, for both the research-engaged and community sectors.

AccessCR notes that many consumers do not identify with or like the word 'consumers'. Though we note the history of the word, consideration should be given to aligning our language with that more common internationally, (or at least encouraging teams the space to negotiate their own preferred terminology when working together).

AccessCR coined the term 'consumer and community research workforce' or CCRew to represent the individuals seeking, taking part in and contributing to research. Through its community connections, it understands that consumers develop in their capacity to inform research over time. Their knowledge and experience will be derived from multiple sources. As they get more experienced, they may find themselves contributing across different types of research, different therapeutic areas, different institutions. They do not necessarily affiliate with a single consumer organisation or research organisation, and their 'professional development' to network and learn from other consumers, researchers, etc is often self-funded.

As the NHMRC reflects on the infrastructure necessary to support consumer involvement in research, it should consider how the consumer workforce may need non-institutionally aligned funding to support their development. This may include, for example, access to scientific literature often behind paywalls, attendance at training courses and conferences (travel and registration costs), membership of organisations to support their professional development (e.g. health consumer organisations). Capacity building of the consumer workforce, that is diverse in all dimensions, will be critical for enabling the Statement to deliver on its purpose. If the research sector requires consumers, then just as it supports development of other research staff, it will need to invest in growing the consumer workforce (or CCRew as we advocate for).

AccessCR would welcome the opportunity to further discuss or support consumer involvement in research.

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