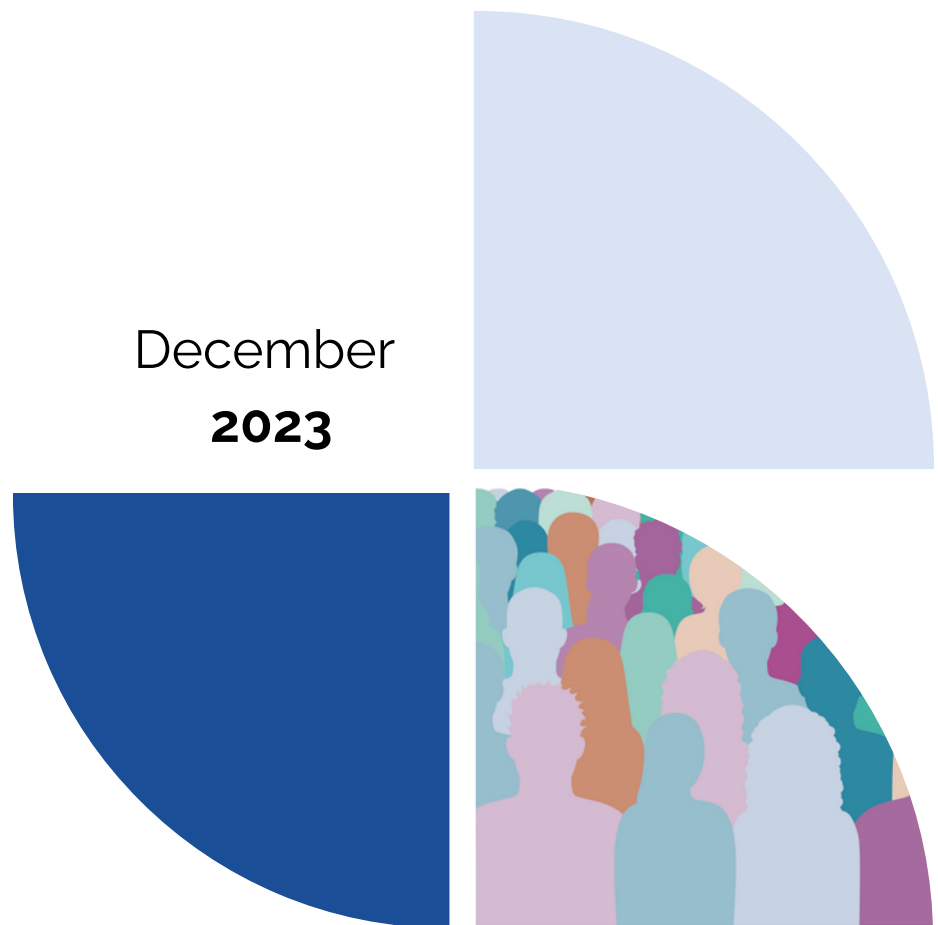Involve Australia's
*Guidelines for Community Involvement
in Genomic Research*

Response to feedback

December
2023

Prepared by
Involve Australia

Involve Australia Project Summary

Involve Australia, a community-led project coordinated by Australian Genomics, is informed by an expert working group which includes patient advocates, patient support and advocacy group leaders and researchers collaborating to give the public a stronger voice in genomic research and its translation into clinical practice. The project aims to inspire and enable people to be involved meaningfully in all parts of genomic research by bringing together patients, broader community representatives, patient support and advocacy groups, and the clinical and research community.

A key outcome of the Involve Australia project is the development of the *Guidelines for Community Involvement in Genomic Research* (hereby after called 'The Guidelines'), which aim to provide genomic researchers in Australia with information for involving community members effectively and meaningfully in research projects. Genomic research brings with it complex ethical, legal and social implications, such as high levels of unmet need for people living with genetic conditions, including diagnosis, access to treatment, and growth of precision medicine and gene therapies. All of which will benefit from the lens of lived experience to facilitate equitable and responsible implementation. Appendix 1 lists the final recommendations presented in The Guidelines.

What informed The Guidelines?
The table below outlines the aims of each of the data collection methods.

Table 1. Guideline data collection methods and aims.

Method	Aims
Scoping review	- Identify Australian community involvement guidelines for health research - Determine how community was involved in guideline development - Determine how community involvement was reported - Determine if guidelines cover all relevant content for implementing community involvement - Determine current level of community involvement in genomics research internationally and how involvement is reported
Health research perceptions survey	Understand the public's perspectives on perception of community involvement in health-related research activities

Method	Aims
Interviews	• Identify barriers and enablers to community involvement from the perspectives of community members, community involvement coordinators, researchers and institute leads • Identify community involvement processes currently being undertaken
Working Group discussions	• Drive the direction of the project • Provide context to data collected

How were community members involved in the development of The Guidelines?

Community members were involved as Involve Australia Working Group members. These individuals are primarily involved in health consumer advocacy groups/organisations. Several members are service users themselves. Other working group members are professional researchers.

The tasks of the Involve Australia Working Group were to progress Involve Australia activities by providing input, and advice on methods used to conduct the scoping review, involve the public effectively, and how best to evaluate the impact of The Guidelines, as well as revision of key output documents before they are made available publicly.

Consultation process and feedback

The Guidelines underwent several reviews. Please see Appendix 2 for a timeline of the entire process.

Public consultation on the draft Guidelines was open from May to June 2023. Involve Australia is extremely grateful to all that took part in the consultation and thank them all for the time and effort they put into providing a response. The detailed and constructive feedback provided was exceedingly useful in shaping the final version of the guidelines.

Several respondents expressed that The Guidelines are well thought out and will be useful for researchers.

"[The Guidelines are] well-researched and it's good that community members' opinions were involved in their justifications."

"Practical and commonsense. Very clear and respectful. I've dealt with consumers before as a researcher, but you have covered things I hadn't thought about/took for granted. Very helpful approach. Relatively easy to implement (for the most part)."

We also received feedback from Patient Support and Advocacy Groups who support The Guidelines and believe they will be helpful for all Australian researchers.

> *"[Patient Support and Advocacy Group] encourages their broad dissemination among the research community, even beyond genomics research. [We] suggests these guidelines are shared widely with academic institutions across Australia and used to educate researchers at all levels."*

In total, there were 46 usable responses (Figure 1). Thirty-three (52%) of these were completed fully, however we also included partially completed responses when addressing feedback. We also received written feedback from three groups.
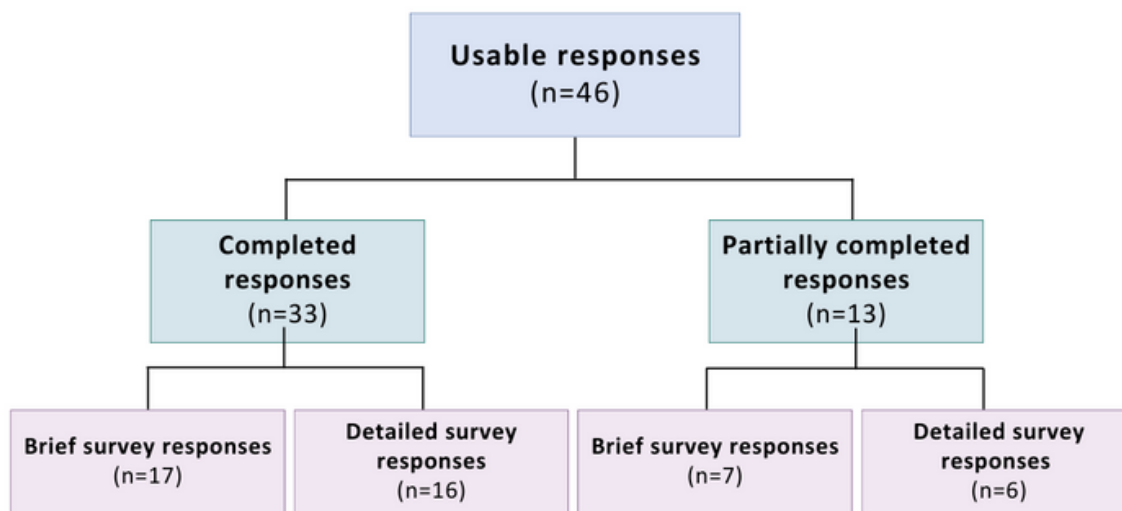

Figure 1. Flowchart of completed vs partially completed survey responses, and brief survey vs detailed survey responses.

We asked survey respondents to select or specify a group/s that best described their role (Figure 2). Multiple selections were permitted. The most represented roles were 'genomics researchers' (n=16), 'genomics health professionals' (n=9) 'patient or consumer representatives' (n=8) and 'patient advocacy and/or support groups' (n=6). 'Other' roles respondents listed included 'community involvement coordinators' and other genomics professionals (e.g. 'education officers', 'project officers', 'project managers').
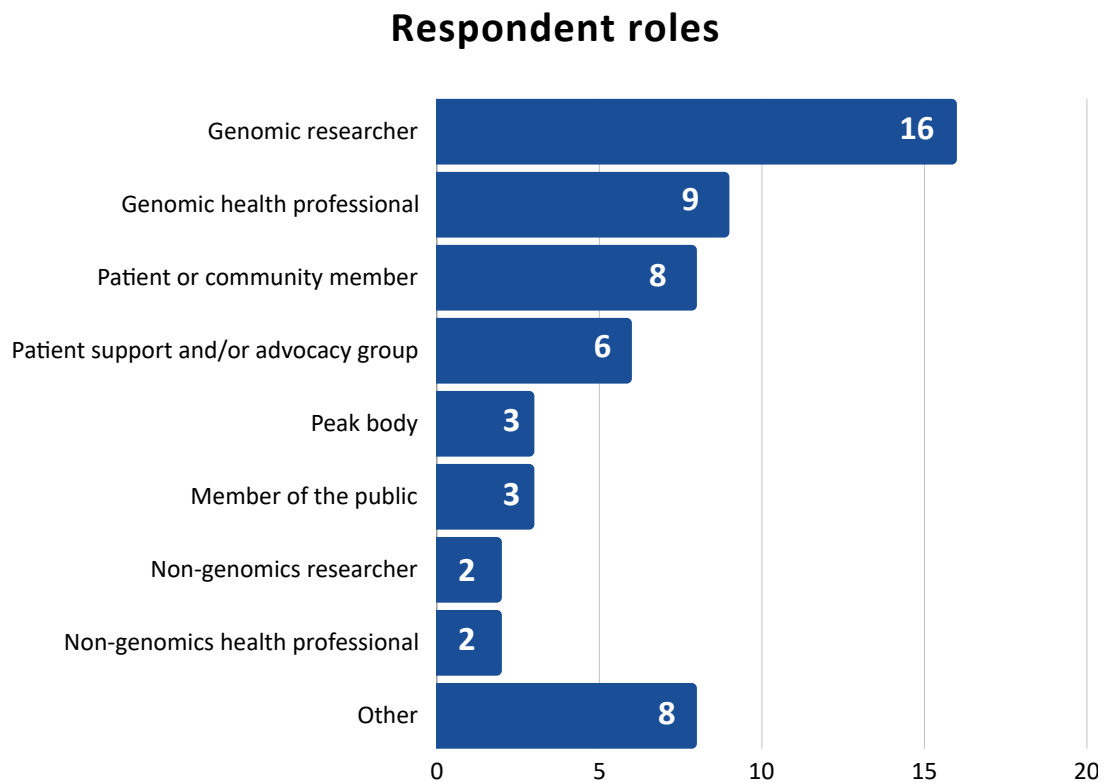
Respondent roles

Role	Count
Genomic researcher	16
Genomic health professional	9
Patient or community member	8
Patient support and/or advocacy group	6
Peak body	3
Member of the public	3
Non-genomics researcher	2
Non-genomics health professional	2
Other	8

Figure 2. Consultation survey respondent roles.

Survey respondents were asked to provide an overall rating of each of the recommendations. All recommendations received more than 80% positive ratings of 'Excellent', 'Very Good' and/or 'Good' (Appendix 3).

Listed in Table 2 are some key feedback themes found throughout consultation survey responses and how they have been addressed.

Table 2. Key consultation feedback themes and how they have been addressed.

Major recurring themes	How they have been addressed
There were several recommendations where background (i.e. evidence) content was presented in the 'how to' section of a recommendation rather than in the content prior.	• Recommendations have been reviewed to ensure 'how to' sections (now called 'Suggestions') only detail practical, implementable steps for genomic researchers to follow.
Edit entire document for brevity and conciseness	• The Guidelines underwent a review by multiple Australian Genomics team members for brevity, conciseness, and proofreading.
Inclusion of the International Association for Public Participation's (IAP2's) public participation spectrum in the document to make it clear what roles consumers can have in research.	• The VCCC Consumer Engagement spectrum was adapted and included in the 'Introduction', with examples of how community members can be involved at each level of the spectrum. • The International Association for Public Participation's (IAP2's) public participation spectrum is referenced as an additional resource.
'Trauma-informed approach' needs a clearer definition	• A more detailed definition for 'trauma-informed' approach was provided. This includes some descriptive language to remind researchers how best to communicate with community (i.e. listen with curiosity and respect). • A definition for trauma more generally has been provided. • The term 'trauma-informed' was removed from the recommendation title to make it more accessible.
Confusion around evaluation of community involvement and how this can be implemented effectively	• This domain was revised to make it clear that community members are not being evaluated on their performance as members on a research team. Rather, researchers are attempting to determine if they are involving community members in the most meaningful and effective way possible.

However, there was feedback specific to two recommendations in the 'Relationship Building' domain and one in the 'Valuing Community members domain. The lowest rated recommendation was regarding remuneration of community members (85% positive rating).

Table 3. Major feedback for specific recommendations.

Building relationships		
Recommendation	**Feedback**	**Response to feedback**
"Involve us as early as possible, we can contribute to all parts of research and can be invaluable in the early stages"	Community involvement should be mandated from the beginning of projects.	Community involvement may be mandated in health research in the future and while this would be a positive move, Involve Australia notes that this is not the reality of the current genomics research landscape. To suggest mandating community involvement at the beginning of all genomics projects would be a significant leap for researchers, institutes, and funding bodies, and there is no current structure to enforce such a mandate. Involve Australia strongly believes that community members have a right to be involved in all projects about them, however these guidelines aim to assist people working in the field where they currently are. Involve Australia aims for these guidelines to be a practical next step for researchers.
"Consider diversity when involving community members. Listening to diverse voices enables research to benefit a greater number of communities"	Recommendation should be more strongly worded and speak to genomics-specific issues (e.g. many genomics projects include CALD members	This recommendation was extensively revised to incorporate historical treatment of CALD communities in genomics and genetics. Additional resources for the CALD community and intellectual disability community have been included.

Valuing community members		
Recommendation	**Feedback**	**Response to feedback**
"Valuing our time is essential therefore an appropriate payment should always be offered. Providing payment allows for a more diverse community member workforce."	Concerns predominantly from researchers on how to manage payment of community members.	Many institutes are successfully paying community members. A resource developed by the Victorian Comprehensive Cancer Centre which outlines their payment process has been included. Involve Australia will also be developing a set of recommendations to institutes, to provide advice on how community involvement can be addressed at this level.

Out of scope feedback

Listed below are suggestions received that are out of scope. We have provided responses as to why these were not addressed in The Guidelines.

Table 4. Consultation feedback that could not be addressed in The Guidelines.

Out of scope feedback	Response to feedback
Suggest education events that all stakeholders (community members included) are invited to	This is something Involve Australia will explore in its next body of work.
List specific meeting processes that should be undertaken when community members are involved on a research team	Rather than specific meeting processes, we ask researchers to communicate with community members in a non-judgemental manner. We emphasise the importance of asking community members their thoughts and listening with curiosity and open-mindedness.
Suggested examples and/or resources specific to a sub-area of genomics (e.g. clinical trial design, specific medical services and technology)	The aim of The Guidelines is to provide general guidance to researchers working across the entire spectrum of genomics research who wish to involve community members. We have pointed to more specific resources where relevant.

Community member review panel

Following the consultation, we invited a panel of community members and patient support and advocacy groups to conduct a final review of The Guidelines to ensure the community voice could still be heard. No major revisions were suggested. Minor suggestions can be found in Table 5 below.

There was some concern about writing from the voice of the community (i.e. using 'us' and 'we' to refer to community members and 'you' to refer to genomic researchers). Specific concerns included potential alienation of researchers and the language confusing readers. After discussion with working group members, it was decided that this language would be retained as The Guidelines are community-led. Through our consultation survey process, only found one genomics researcher who suggested a change in this language. To avoid confusion, we have refined the language and used formatting to highlight the 'us' and 'we' language style.

Table 5. Minor suggestions from community member review panel

Minor suggestions include:
Number recommendations and recommendation domains for easier referencing throughout the guidelines
Emphasise the difference between involvement and engagement towards the beginning of the guidelines
Revise written language to ensure it is more plain language, and therefore more concise for readers. This also reduced repetitiveness
Elaborate where appropriate, including the addition of specific 'Suggestions' to assist researchers in their community involvement processes

Future of The Guidelines

Following the launch of The Guidelines in December 2023, the Involve Australia Working Group will pilot and evaluate the effectiveness of The Guidelines in practice. Genomics research projects partnering with Australian Genomics will be requested to join the implementation phase of the Involve Australia project. This evaluation will occur over the next two years.

Appendix 1. Involve Australia's Final Recommendations for Community Involvement in Genomic Research

1	Building relationships
1.1	Connect with us.
1.2	Initiate and maintain a meaningful and respectful partnership with us.
1.3	Involve us as early as possible; we can contribute to all parts of the research and can be invaluable in the early stages.
1.4	Diversity and inclusion when involving community members is essential for equitable health outcomes. Listening to diverse voices enables research to benefit a greater number of communities.
1.5	Communication is a two-way process integral to effective research. Developing a communication plan with input from us, for participants and the broader community will promote well informed and acceptable research.
1.6	Discuss with us how we would like to be identified within a project. This will help foster mutual respect.
2	Setting expectations
2.1	Discuss with us whether we will represent ourselves or a specific community. Making this clear will determine whether we are the right fit and inform our involvement in the project design.
2.2	Every community member is different and will require different approaches to support involvement. Discuss with us how we would like to contribute.
2.3	We are experts in our lived experience but may not be familiar with genomics. Take the time to provide contextual information on the project and genomics more generally, if needed.
2.4	Co-create a shared core goal(s) for the project. This will allow us to work together with a clear objective and help shape our role(s) within the project.

3	**Valuing community members**
3.1	Valuing our time is essential, therefore an appropriate payment should always be offered. Providing payment allows for a more diverse community member workforce.
3.2	We may choose to get involved because of lived experience, and we will draw on these experiences to inform our contributions. Approaching our involvement with respect and in a non-judgemental way can provide a safe, inclusive environment.
3.3	Acknowledging the contributions we make demonstrates our value as members of the research team. Discuss with us how we would like our efforts acknowledged.
4	**Evaluating and reporting on your community involvement process**
4.1	Community involvement practices and the impact of involvement should be evaluated throughout the project. This encourages project teams to reflect on and adapt involvement processes.
4.2	Report publicly on how we were involved as community members to demonstrate to researchers and the public the value and impact of our involvement in genomic research.
5	**Translating your research outcomes into real-world impact**
5.1	Translation of research findings into real-world changes can directly benefit the community. Draw on our lived experience for translation that meets the needs of our communities.
5.2	We may have a strong network with our communities. Include us in conversations about sharing research findings with those who will be impacted by them.

07/2021 to 01/2023

Data collection

Data was collected via a review of existing community involvement guidelines, key informant interviews and a public perceptions of health research survey.

07/2022 to 02/2023

Drafting

Data was analysed and discussed with the working group to develop key domains of The Guidelines. Recommendations were drafted according to these domains and refined with the working group.

05/2023 to 06/2023

Consultation

The drafted guidelines were released for public consultation. Respondents were asked to complete a survey and provide ratings for each recommendation and domain.

09/2023

Community review

The Guidelines underwent extensive revisions. Several community members were asked to provide a final review of The Guidelines to ensure the community voice was still present.

Relationship building
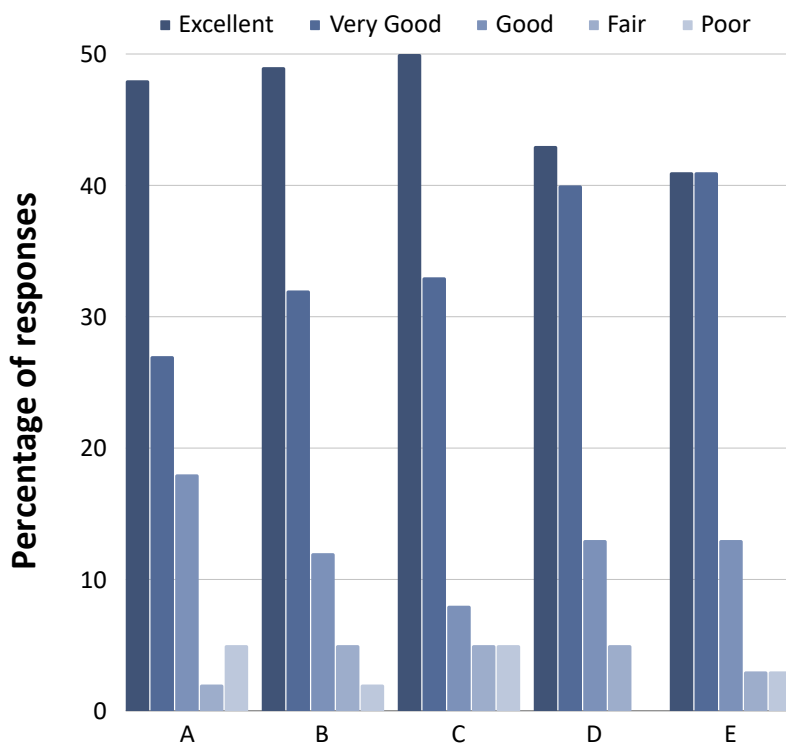
A: Build respectful relationships with us that allow for an open dialogue.

B: Involve us as early as possible, we can contribute to all parts of research and can be invaluable in the early stages.

C: Consider diversity when involving community members. Listening to diverse voices enables research to benefit a greater number of communities.

D: Communication is a two-way process that is integral to meaningful research. Co-designing a communication plan for participants and the broader community will promote well informed and acceptable research.

E: To foster mutual respect, discuss with us how we would like to be identified in a project.

Setting expectations
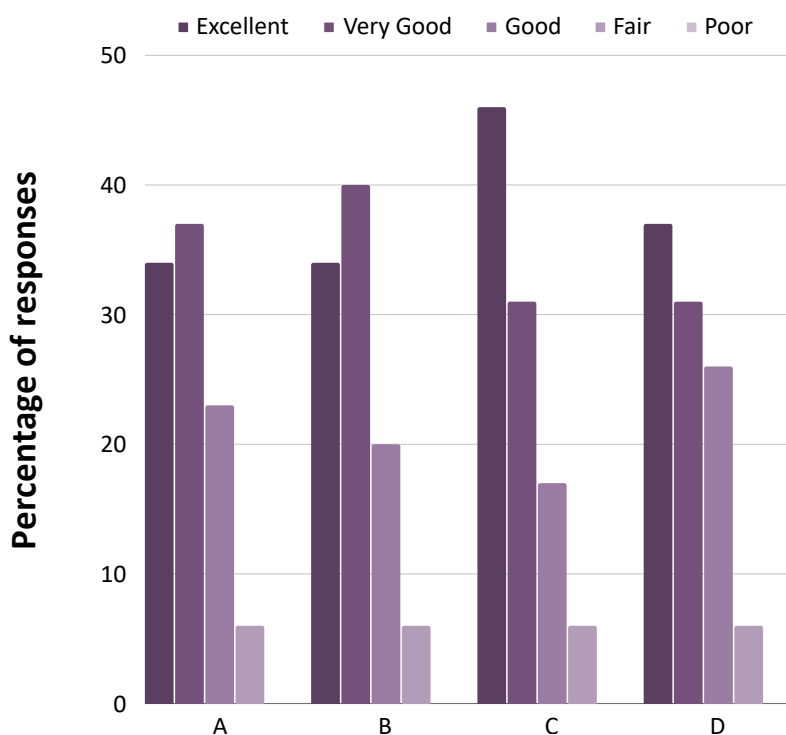
A: Decide whether we will represent ourselves or a specific community. Making this clear will determine whether we are the right fit, and inform involvement design.

B: Every community member is different and will require different things. Discuss with us how we would like to contribute and what can support our involvement.
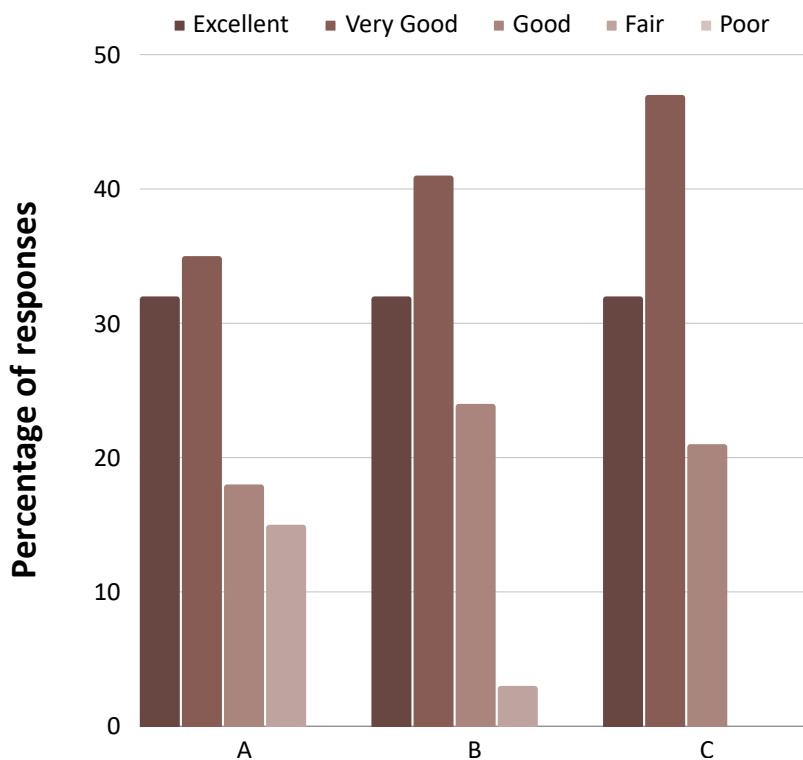
C: We are experts in our lived experience but may not be familiar with genomics. Take the time to improve our knowledge on the project and genomics more generally.

D: Agree on a shared core goal(s) for the project with our input. This will allow us to work together with a clear objective and help shape our role(s) within the project.
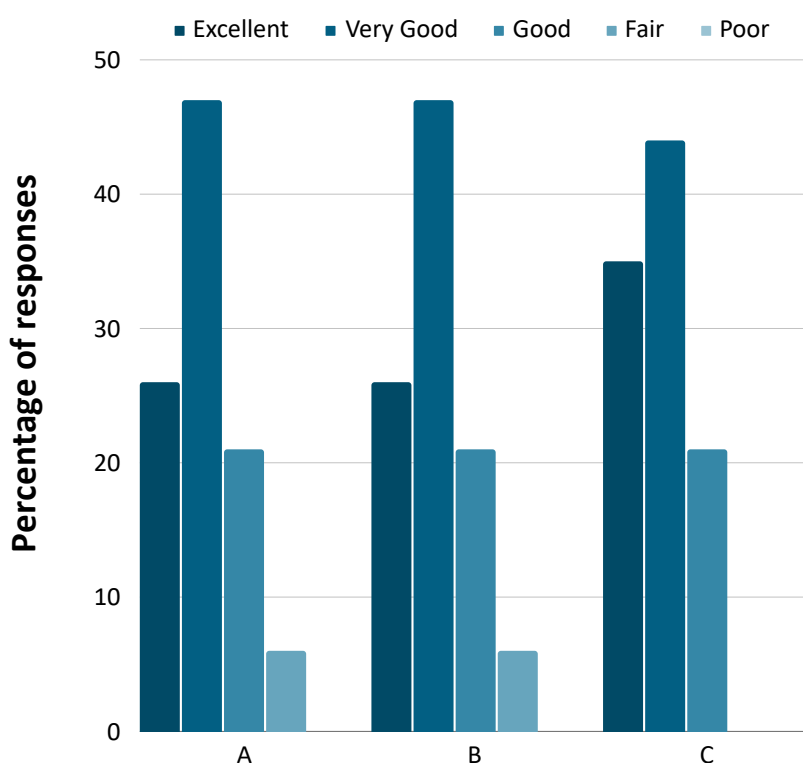
Valuing community members

A: Valuing our time is essential, therefore an appropriate payment should always be offered. Providing payment allows for a more diverse community member workforce.
B: We may get involved because of personal experience and will draw on these experiences to inform our contributions. Using a 'trauma-informed' approach can provide inclusive and appropriate support.
C: Acknowledging the contributions we make demonstrates our value as members of the research team. Discuss with us how we would like our efforts acknowledged.

Evaluating and reporting

A: How we are being involved should be evaluated throughout the project. This encourages continuous reflection and adaptation of the involvement process.
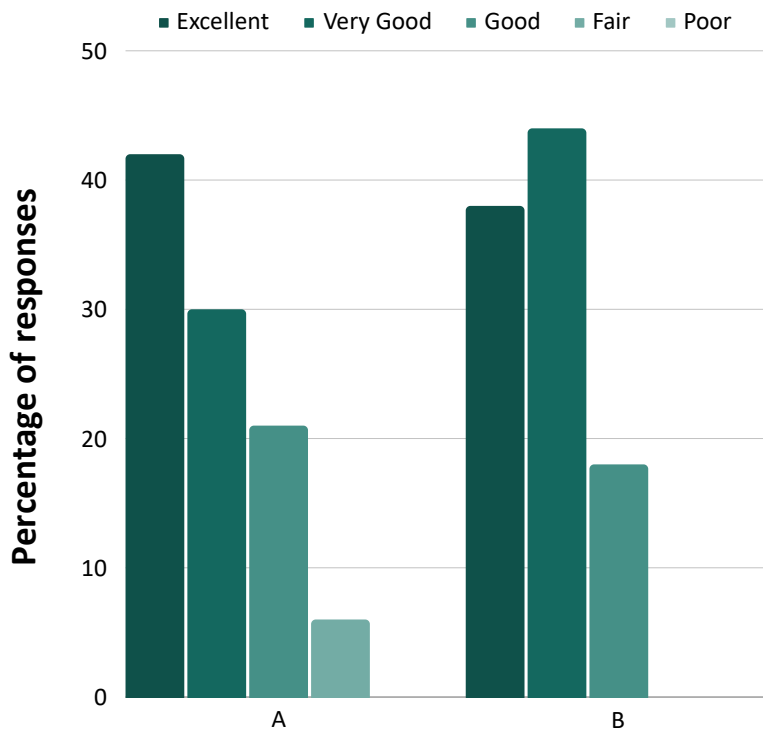**B:** Our roles as community members can change over the course of a project. It is important to re-evaluate our roles to ensure it aligns with any changes in scope.
C: Report publicly on how we were involved as community members to demonstrate to researchers and the public the value and impact of our involvement in genomics research.

Real-world applications

A: Translation of research findings into real-world changes can directly benefit the community. By drawing on our lived experience we can inform translation so that it meets the needs of the community.
B: We may have a strong network with our community. Include us in conversations about sharing research findings with those that it will impact.