Australian Multicultural Health Collaborative

Our cultures
Our languages
Our health

Consultations on the National SOPs for Clinical Trials

June 2026

About

The Australian Multicultural Health Collaborative (the Collaborative) is the national multicultural health peak body.

Vision Statement: *In a truly multicultural Australia, our health and social care system is committed to health equity, and works proactively towards sustained improvement in the physical, mental and spiritual health and wellbeing of our multicultural communities.*

The Collaborative is an initiative of the Federation of Ethnic Communities' Councils of Australia (FECCA). We provide a national voice, leadership and advice on policy, research, data, and practice to improve access and equity, address systemic racism, and achieve better health and wellbeing outcomes for Australians from multicultural backgrounds.

The Collaborative is representative, and membership based. Members include consumers and carers; health services and wellbeing/social care services; practitioners; and researchers. The Collaborative also welcomes as affiliates other national health peak organisations.

1. About FECCA

FECCA is the national peak body for Australians from multicultural backgrounds, representing more than 1,500 community organisations. FECCA advocates for policies that promote equity, inclusion, and wellbeing for all Australians regardless of cultural or linguistic background. Throughout this submission, 'multicultural communities' refers to Australians from culturally and linguistically diverse (CALD) backgrounds – those born overseas or with a parent born overseas, or who speak a language other than English at home. According to the 2021 Census, this describes more than half of all Australians.

FECCA has direct, documented experience in health research equity for multicultural communities. FECCA is a contributor to 'We are not invited', a landmark study funded by the Australian National Health and Medical Research Council (NHMRC) cited throughout this submission, and to the Australian Clinical Trials Alliance (ACTA) 2023 recommendations on multicultural trial participation. FECCA co-hosted a national roundtable on ethical research with ageing multicultural communities, engaging directly with the NHMRC National Statement on Ethical Conduct in Human Research that underpins these Standard Operating Procedures (SOPs).

2. FECCA and AMHC's Central Concern

Multicultural Australians are systematically underrepresented in clinical trials – not as a result of deliberate exclusion, but as a consequence of systems that were not designed with them in mind.

'We are not invited', an NHMRC-funded study co-authored by FECCA's own representative, asked 158 adults from 21 ethnically diverse communities across Australia about their experience with clinical trials. Communities consulted included Tamil, Greek, Punjabi, Italian, Mandarin, Cantonese, Vietnamese, Nepalese and Arabic-speaking communities, across six capital cities and one rural town (Brijnath et al., 2024). Only three of the 158 participants had ever taken part in a trial. Participants were not unwilling; they recognised the value of research, were prepared to participate, and offered concrete suggestions. They had simply never been asked.

This finding reframes the problem. Multicultural communities face real and persistent barriers to trial participation that require skilled navigation and trusted community relationships to overcome. This is precisely the role that FECCA and the AMHC are positioned to play. The three conditions necessary for genuine inclusion

are co-designing the engagement process, building trust, and investing the time. Not one of these is currently required by the National SOPs. They are, however, central to FECCA and the AMHC's work.

The scale of exclusion is documented. A retrospective analysis in South West Sydney, one of Australia's most culturally diverse regions, of 19,453 cancer patients found multicultural trial participation at 5.7%, compared to 8.4% for non-multicultural patients. Those whose preferred language was not English were less than half as likely to participate (Smith et al., 2017). In 2025, the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) published a self-critical audit finding low multicultural representation across its own trial portfolio, identifying the absence of translated materials and interpreter access as significant barriers (Ayton, 2025). Multicultural representation in Australian health journals declined from 2.1% in 2010 to 1.1% in 2023 (Skouteris, 2023).

These findings span different disease types, health districts, and research groups. As the lead researcher at Liverpool Hospital has stated: 'When you don't include everyone, the science you produce doesn't represent the community. It's a distorted picture and the results are not generalisable' (Pal, 2023).

FECCA and AMHC's community consultation work, including consultations conducted through the MAE program between 2022 and 2025, and the 'We are not invited' study identify the same four structural barriers:

Language and consent: consent forms and clinical communications are almost universally in English only. Participant Information and Consent Forms written in dense, technical language serve to protect institutions rather than inform participants and this problem persists even when materials are translated. Participants in the 'We are not invited' study specifically noted: 'If some study is targeting a multicultural community, then why should it be in English? It should be in multiple languages' (Sikh focus group participant, in Punjabi). Low English proficiency is the primary factor explaining lower multicultural trial participation in Australia (Pal et al., 2023).

Recruitment: community leaders, ethno-specific health organisations, language schools, and religious institutions are the trusted channels through which multicultural communities expect to hear about research, not online advertising or mainstream clinical networks. As one participant stated: 'The key thing is that you identify the community leaders, and through them you will be able to access all the different types of group organizations or community groups, that is probably the best way' (Vietnamese focus group participant). Trial recruitment that bypasses these channels structurally excludes the communities it fails to reach.

Trust and data concerns: discrimination based on ethnicity remains prevalent in Australian healthcare settings, making it feel unsafe for some community members to disclose their cultural background. This extends to concerns about data: 'Where is the blood going to?' (Chinese focus group participant, in Mandarin). There is currently no specific training in clinical trials terminology for healthcare interpreters in Australia (Pal et al., 2025), compounding the communication gap.

Data invisibility: trials are not required to record participants' cultural or language background. Of the 15 dementia trials published in Australia between 2016 and 2018, 10 reported no ethnicity-related data at all. Without this data, underrepresentation cannot be measured or addressed. As FECCA's 2020 CALD Data Issues Paper established: if we don't count it, it doesn't count.

One Afghan Hazara participant in the 'We are not invited' study captured both the community's willingness and its invisibility to the system: 'Why we participate here, it's not only for our body or the Afghan body, but also good. This research maybe something finds for all the human, for everyone… we are ready to participate.' FECCA's own Multicultural Advocates for Inclusive Aged Care (MAIAC) consultations with more than 400 people from over 40 ethnic communities reflect the same pattern:

'The system assumes you know what to ask, and that's not fair.' (Chinese community member, 85, MAIAC consultation) – systems designed for those already familiar with them, excluding others from the outset.

‘Many in our community are suspicious of government involvement because they fear it means taking loved ones away.’ (Hungarian community member, 68, MAIAC consultation) – institutional distrust that manifests in the clinical trials context as reluctance to participate and to report adverse events.

The consequence extends beyond access. FECCA’s COVID-19 Response Inquiry Submission (2023) documented higher mortality rates among overseas-born Australians, delayed health communications, and the inability to track disproportionate impact in real time. In clinical trials, the same exclusion affects the validity and safety of the evidence base for the entire population.

Australia’s ambition to be a preferred global destination for clinical trials strengthens the case for reform. The revised ICH Guideline for Good Clinical Practice E6(R3), one of the documents the National SOPs are being updated to reflect, already requires sponsors to justify the exclusion of any participant group. FECCA’s recommendations give that standard practical effect in the Australian context.

3. Evidence base

FECCA and AMHC publications: Developing an Ethical Framework for Research with Ageing CALD Communities (2018); CALD Data Issues Paper – ‘If we don’t count it, it doesn’t count’ (2020); COVID-19 Response Inquiry Submission (2023); Response to the Review of the National Medicines Policy (2024); ABS Consultation on Cultural and Ethnic Classifications – AMHC (2025); Multicultural Access and Equity Community Consultations Report (2025); Pre-Budget Submission 2026–27.

External publications: ‘We are not invited’: Australian focus group results on how to improve ethnic diversity in trials – Brijnath et al., Journal of Clinical Epidemiology (2024); Recommendations to Improve Cultural and Linguistic Diversity in Clinical Trials – ACTA (2023); ICH Guideline for Good Clinical Practice E6(R3) – ICH (2025); Lower trial participation by CALD cancer patients is largely due to language barriers – Smith et al. (2017); Improving Access to Cancer Clinical Trials for Patients from CALD Backgrounds in Australia – Pal et al. (2023); Improving Ethnic Diversity in Cancer Trials Through Healthcare Interpreter Training – Pal et al. (2025); Painting a bigger picture: The importance of cultural diversity in clinical trials – Ayton, Monash Lens (2025); Including multicultural communities in health research – Skouteris (2023).

4. What works in the draft SOPs

The draft SOPs contain meaningful advances: an equity and inclusion principle in SOP 02; cultural safety as a named training principle in SOP 03; inclusive design requirements in SOP 04; and an explicit consent principle in SOP 09 requiring that supports including interpreters and translated materials be provided where required. These represent genuine progress. FECCA and AMHC’s recommendations are directed at giving these principles procedural force.

5. Where the draft SOPs fall short: principles without procedures

Across the draft, equity and cultural safety appear in principles sections but not in the procedural requirements that give those principles effect. Policies set expectations – but procedures are what ensure those expectations are consistently applied.

SOP 09 is the clearest example. Its principles state that appropriate supports ‘must be provided where required.’ The consent procedures in sections 9.1 to 9.3 specify nothing about: who determines when interpreter support is required; what constitutes an appropriate interpreter; whether Participant Information and Consent Forms must be in languages other than English; how interpreter use must be documented; or how to manage consent where participants’ cultural context involves family members in medical decision-making. Without procedural specificity, ‘where required’ defaults to investigator discretion and the participation data shows that discretion has consistently defaulted to majority-population practice.

6. FECCA and AMHC Recommendations

Recommendation 1: SOP 01 – Include multicultural community representation in the SOP governance process

SOP 01 governs the development and review of the National SOPs. Multicultural community representation is absent from this process. The current revision has been conducted without the communities the SOPs affect, and the participation data makes clear what that omission costs. Government, regulators, funders, and publishers must allow for greater innovation and flexibility in their processes to enable ethnic diversity in trials to improve (Brijnath et al., 2024). The National SOPs are precisely such a process.

Recommendation: Amend section 1.1 to require multicultural consumer and community representatives as standing participants in the SOP review process. FECCA and the AMHC are available to contribute. The COVID-19 CALD Health Advisory Group provides a proven co-governance model for how this can be operationalised.

Recommendation 2: SOP 02 – Require documented multicultural inclusion strategies from investigators

SOP 02's equity principle requires investigators to promote equitable access, but sections 2.1 to 2.5 contain no mechanism to document how this has been addressed. The participation gap documented in South West Sydney is a direct consequence: no one was required to explain why multicultural communities were not being recruited.

Recommendation: Amend section 2.2 to require investigators to prepare and file a multicultural inclusion strategy prior to trial commencement, covering: the demographic profile of the catchment population; steps proposed to reach multicultural participants; any planned cultural or language adaptations; and, where no CALD-specific measures are taken, a documented justification. This strategy should be retained in the Study Master File.

Recommendation 3: SOP 03 – Establish minimum standards for cultural safety training

SOP 03 identifies cultural safety as a training principle but specifies no minimum content, competency standards, or documentation requirements. There is currently no training in clinical trials terminology available for healthcare interpreters in Australia (Pal et al., 2025). Research confirms that participants from their own cultural group improve comfort and trust, and that navigating sensitive topics in clinical settings requires specific skills that cannot be assumed (Brijnath et al., 2024). Without minimum standards, a training requirement can be met on paper without substantive effect.

Recommendation: Amend section 3.2 to specify minimum cultural safety competency requirements for trial site staff: working with professional interpreters in clinical settings; understanding structural barriers to multicultural participation; CALD health literacy; and culturally adapted consent processes including family-mediated decision-making. This training must be documented alongside Good Clinical Practice (GCP) and other mandatory requirements. FECCA and the AMHC are available to advise on competency frameworks.

Recommendation 4: SOP 04 – Embed multicultural inclusion requirements in protocol development

SOP 04's inclusion principle is not reflected in the protocol development procedures in section 4.1. Trial protocols determine eligibility criteria, site selection, and participant-facing materials before recruitment begins – decisions that cannot be revisited once a trial is underway. Community consultations confirm that participation requiring travel far from home, or to locations inaccessible by public transport, deters engagement even when costs are reimbursed; and that online advertising is viewed unfavourably, particularly by older participants. These are protocol-level decisions that must be made at the design stage.

Recommendation: Amend section 4.1 to require all trial protocols to include a multicultural inclusion strategy covering: the demographic profile of the target population; site selection rationale with reference to multicultural community access; language requirements for participant-facing materials; and any cultural adaptations to trial processes. This strategy should be submitted to the Human Research Ethics Committee (HREC) as part of the ethics application.

Recommendation 5: SOP 09 – Establish procedural requirements for accessible and culturally appropriate informed consent

Informed consent is the foundation of ethical research. Research confirms that lack of linguistic translation diminishes both the quality of consent and the quality of data – and that translated materials had symbolic value, signalling to participants that their participation was welcomed (Brijnath et al., 2024). Critically, large volumes of written material deter participation even in a preferred language: participants recommended graphics, videos, and audiovisual materials to communicate study information. A consent form in English, presented without interpreter support to a participant whose preferred language is Arabic or Vietnamese, does not meet the standard of informed consent.

SOP 09's principles acknowledge this, but the consent procedures in sections 9.1 to 9.3 provide no guidance on operationalising it. The increasing use of digital consent platforms introduces further barriers for participants with limited English proficiency or digital literacy that are also unaddressed.

FECCA and AMHC's priority ask for SOP 09:

Core recommendation: Amend section 9.1 to require investigators to assess the language profile of the anticipated trial population; confirm and document access to accredited interpreter services before the trial opens to recruitment; record interpreter use in the consent documentation; and allocate adequate time for interpreter-supported consent. Amend section 9.2 to include guidance on consent where family members play a cultural decision-making role which is the norm in many multicultural communities.

Secondary recommendation: Require Participant Information and Consent Forms in languages appropriate to the trial population, and that where digital platforms are used for consent or data collection, accessibility for participants with limited English proficiency or digital literacy is documented. FECCA and AMHC are open to working with the IGPRG on proportionate implementation, including: a central interpreter register; shared translated consent templates; and tiered requirements by trial scale.

Recommendation 6: SOP 12 – Address multicultural participant safety in monitoring and reporting

SOP 12 does not address the risk that multicultural participants may under-report adverse events due to language barriers, cultural norms around disclosure, or institutional distrust. The same distrust that reduces participation also reduces willingness to report problems during a trial. Undetected adverse events in multicultural participants represent both a direct safety risk and a data integrity risk for the trial as a whole.

Recommendation: Amend SOP 12 to require safety monitoring plans to address multicultural participant populations, including: assessment of whether language barriers may affect adverse event reporting; multilingual safety reporting pathways; proactive follow-up protocols where communication difficulties have been identified during the trial; and training for site staff on recognising communication barriers in safety reporting contexts.

Recommendation 7: SOP 14 – Require collection and reporting of multicultural demographic data

Trials in Australia are not required to record participants' cultural or language background. The South West Sydney analysis was only possible because that study specifically collected CALD demographic data. Without a national mandatory requirement, that level of insight remains the exception. Research confirms that participants are prepared to share cultural and ethnic data where clear justification is provided and rapport is established. The barrier is not community resistance, but the absence of any requirement to collect it.

Section 14.4.3 contains a commendable provision on Aboriginal and Torres Strait Islander data sovereignty. No equivalent exists for multicultural communities, and section 14.4.2 does not identify cultural or language background as standard data elements.

Recommendation: Three amendments to SOP 14: first, amend section 14.4.2 to require all trial databases to collect country of birth, preferred language, language spoken at home, and whether an interpreter was required, aligned with ABS standards; second, require trial reports to disaggregate participation and outcome data by these

fields; third, amend section 14.4.3 to include a parallel multicultural community data provision consistent with the existing Aboriginal and Torres Strait Islander provision.

References

FECCA publications (available at fecca.org.au):

Developing an Ethical Framework for Research with Ageing Culturally and Linguistically Diverse Communities. FECCA, AAG & NARI, 2018. fecca.org.au/updates/developing-an-ethical-framework-for-research-with-ageing-cald-communities/

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Including multicultural communities in health research. Skouteris, 2023. nsw.gov.au/departments-and-agencies/transcultural-mental-health-centre

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