BMC Medical Ethics

RESEARCH Open Access

# Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study

Nathan Higgins[1,2*], Brette Blakely[3†], Roland Everingham[4†], Frederic Gilbert[5†], Sarah Griffin[6†], Alexander R. Harris[7†], Sally Herring[8,9†], Calvin Wai Loon Ho[10,11,12†], Kate Hoy[8,9†], Scott Kiel-Chisholm[13†], Julian Koplin[2†], Sharon Lawn[14†], Allan McCay[15†], Nitya Phillipson[16†], Bernadette Richards[17†], Jeffrey V. Rosenfeld[18,19†], Ehsan Shamsi Gooshki[2†], John Noel Viana[20†], John Gardner[2,21] and Adrian Carter[1,2]

## Abstract

The clinical development of implantable neural devices raises complex ethical questions about post-trial responsibilities to participants. Continued support for participants who continue to use investigational implantable neural devices requires ongoing specialist care, technical expertise, access to tertiary clinical infrastructure, and substantial financial resources to pay for the device and related procedures. However, continued access may not be possible if the trial shows no benefit, if financial barriers limit commercial viability, or if safety concerns lead to suspension or early termination. Specific ethical guidance on post-trial responsibility is urgently needed. To address this challenge within the Australian innovation context, we conducted a modified Delphi study with a multidisciplinary panel of 24 experts, including representatives from industry, bioethics, law, neurosurgery, clinical psychology/neuropsychology, clinical research, neural engineering, regulation and governance, and lived experience advocacy. The process involved two workshops and a survey, guided by established RAND/UCLA methods with context-specific modifications. Drawing on prior empirical research and regulatory review, the panel developed 11 consensus recommendations for responsible post-trial practices. All recommendations achieved high levels of agreement and were rated as highly important for addressing ethical risks in the Australian environment. These are the first jurisdiction-specific recommendations of their kind, and we anticipate they will substantially enhance ethical and practical standards for post-trial responsibility in implantable neural device research in Australia and internationally.

**Keywords** Recommendations, Post-trial responsibility, Neuroethics, Implantable devices, Research ethics

[†]Scott Kiel-Chisholm, Julian Koplin, Sharon Lawn, Allan McCay, Nitya Phillipson, Bernadette Richards, Jeffrey V. Rosenfeld, Ehsan Shamsi Gooshki, John Noel Viana, Brette Blakely, Roland Everingham, Frederic Gilbert, Sarah Griffin, Alexander R. Harris, Sally Herring, Calvin Wai Loon Ho and Kate Hoy contributed equally to this work.

*Correspondence:
Nathan Higgins
nathan.higgins@monash.edu

Full list of author information is available at the end of the article

## Background

Neurotechnology innovation is creating promising opportunities to alleviate the global burden of neurological and psychiatric diseases [1]. Annually, billions of dollars in private investment and public funding are being poured into the development of novel devices for treating these conditions [2].

This study focuses on implantable neural devices: a family of complex, specialised, multi-component medical devices mostly used to treat intractable and debilitating manifestations of disease. These devices function by modulating, monitoring and/or decoding the activity of the central or peripheral nervous system. Paradigmatic implantable neural devices include deep brain stimulation (DBS) for treating movement disorders (e.g., Parkinson's disease) and severe psychiatric conditions [3, 4]; and brain-computer interfaces (BCIs) that enable direct communication between the brain and an external device by recording, decoding, or stimulating neural activity. Investigational BCI systems have been shown to restore movement and enable limited pixelated vision in blind individuals [5], as well as provide new means of communication and interacting with the world [6–9].

Clinical investigations of implantable neural devices often have study designs that include inpatient hospital stays for device-related surgeries and several years of outpatient follow-up for device monitoring [10–12]. One underaddressed ethical consideration that arises from the nature of how these trials are designed is whether, and to what extent, participants enrolled in clinical trials should be supported to continue using implantable devices after the trial has ended (whether planned or prematurely). Commentators agree on a few key points. For example, there is general agreement that research participants – who accept considerable risks and burdens to participate in trials of implantable systems – must be informed about what arrangements for post-trial support will be in place, and must not be discharged from the trials without some follow up support [13–15].

However, there remains considerable uncertainty and debate over who should be responsible for providing, funding and governing post-trial support for users of investigational implants [16–18]. Some have argued that participants implanted with devices are owed continued support because they accept high levels of risk and burdens to participate in the trial, and would be exposed to significant harm and distress if they were to lose devices that were benefitting them [19, 20]. But implantable neural devices are complex and expensive interventions that require a multidisciplinary care and specialist clinical services to support their use. Given the significant and long-term resource demands of providing ongoing support for participants who continue to use irreversible and potentially lifelong trial devices, there is still no consensus about the extent of support that should be required of key trial stakeholders, including investigators, sponsors, institutions, regulators, and insurers [18].

The need for ethical guidance on this issue is becoming increasingly urgent as clinical trials of implantable neural devices are growing in size and in number. Several high-profile start-ups – including Blackrock Neurotech, Neuralink, and Synchron – are competing to be the first to bring an implantable BCI system to market. These companies will soon begin recruiting patients for multi-site pivotal trials to generate data for regulatory approval. Against this backdrop of accelerating research and investment, there have been a number of concerning reports of participants experiencing psychological harm and distress as a result of losing access to investigational implantable devices after the trial [21–25]. The harms caused to participants in these situations is only beginning to be investigated [26]. Without specific ethical guidance on this issue, trial organisers will continue to navigate post-trial responsibility in an ad hoc manner or rely on outdated international frameworks that have changed minimally since the early 2000s [27–29].

One avenue for progress is multidisciplinary consensus on the core questions, concepts and normative foundations that define this problem. We are not the first to recognise the importance of multi-stakeholder consensus on the problem of post-trial responsibility [14, 27, 30, 31]. A recent multidisciplinary exercise by van Stuijvenberg and colleagues outlined recommendations on the use of investigational implantable neural devices in clinical trials, including several recommendations on ethical post-trial support [32]. These recommendations target researchers and research ethics committees as key trial stakeholders and they were shaped by existing international standards and regulations.

A critical challenge to developing actionable ethical guidance for study design and coordination is acknowledging the extent to which post-trial considerations are shaped by the trial's geographic or jurisdictional context of the clinical trial. While the challenge of accounting for these contextual factors has already elsewhere been recognised, to our knowledge it has not been extensively addressed in the bioethics literature. For example, in a recent workshop on the post-trial use of implantable devices it was observed that "conversations became increasingly speculative when we considered the questions about the extent of care required, and which stakeholders are most responsible" [28], and that meaningful progress would require "a full complement of stakeholders at the table". Similarly, a recent analysis of this issue by Goering and colleagues notes that defining the practical "what" and "how" of post-trial responsibilities is "a complex task that requires input from stakeholders across

many different organizations and areas of expertise and needs to be contextualised" [18].

If left unresolved, the problem of post-trial responsibility poses significant risks to prospective trial participants and a threat to innovation in the field. We conducted a collaborative, multidisciplinary exercise focused on developing recommendations for post-trial responsibility in Australia. Our aim was to conduct a consensus exercise situated within a national context to facilitate a focused analysis of this complex problem. Australian biomedical innovation represents a distinctive jurisdictional and regulatory context: despite a relatively small population of 27 million in 2025, the country remains a global leader in biomedical research having notably commercialised the first cochlear implant in the 1980s and developed the Stentrode and Minder BCI technologies in late 2010s [33–35]. Though Australia has recognised difficulties translating and commercialising local biomedical innovations [36], the country is reputed for its world-leading universal healthcare system and favourable environment for first-in-human research supported by fast-track regulatory exemption processes and tax incentives [37]. As such, the particularities of the Australian system (which include universal healthcare and a favourable environment for first-in-human research, supported by fast-track regulatory exemption processes and tax incentives) must be then taken into account when translating the articles findings of this research to other jurisdictions.

**Table 1** Demographics of multidisciplinary panel

| **Participants (n = 24)** | |
|---|---|
| Expertise | |
| Bioethics or philosophy | 10 |
| Law, regulation, trial governance and health economics | 5 |
| Industry | 3 |
| Clinical psychology/neuropsychology, clinical research | 2 |
| Neurosurgery, neurology, psychiatry | 1 |
| Bioengineering, neural engineering | 1 |
| Social science | 1 |
| Lived-experience, consumer advocacy | 1 |
| Gender | |
| Man | 12 |
| Woman | 11 |
| Prefer not to say | 1 |
| Organisational affiliation in Australia | |
| Victoria | 12 |
| New South Wales | 6 |
| Queensland | 3 |
| Tasmania | 1 |
| South Australia | 1 |
| Australian Capital Territory | 1 |

## Methods

We employed a modified Delphi approach to develop consensus recommendations on post-trial responsibility. Delphi methods are well-established for building consensus on topics of interest via multiple rounds of group and individual feedback [38, 39]. Our study had three stages: two 2.5-hour multidisciplinary workshops and a follow-up survey. This study design is similar to the RAND/UCLA Delphi method widely used in health policy and research priority setting [40–42]. The RAND/UCLA Appropriateness Method (RAM) integrates the best available evidence with expert clinical judgment to assess the appropriateness of medical procedures for specific patient scenarios [41]. It involves a thorough literature review followed by an independent survey and a final structured group discussion. We made some adaptions to this method to better align with our aims. Most notably, participants were identifiable to one another in both workshops, which allowed for open and direct verbal discussion where disagreements could be clearly expressed and mutually understood. Similar modifications to the RAND / UCLA design have been employed elsewhere in studies that employ empirical bioethics methodologies [43].

Extensive research and preparatory work were conducted by the core team (NH, AC, JG), including an international survey of current practices in implantable neural device research [28] and in-depth semi-structured interviews with trial investigators. The workshop activities were designed and facilitated by NH, AC, JG and LR. This consensus exercise complied with the ACCORD Consensus Reporting Document, but was not pre-registered [44]. This study was approved by Monash University Human Research Ethics Committee (ID: 31526).

### Selection of panellists

A multidisciplinary expert panel ($n = 24$) was convened by invitation. Most panellists co-authored the final paper with the core team, and the contributions of remaining members can be found in the Acknowledgements. Several factors were considered in the selection of experts (see Table 1 for demographic data). We purposively invited experts working in Australian research or clinical practice, or with significant familiarity or professional experience in the Australian context. Disciplines represented included bioethics, law, health economics, neurosurgery, clinical psychology/neuropsychology, clinical research, neural engineering, clinical trial regulation and governance, industry, and lived experience advocacy. We also sought a diversity of expertise with various kinds of clinical research and device types (e.g., clinical neuromodulation research, lab-based BCI research). Although the panel included lived experience and disability advocates, it did not include any individuals with lived

experience as a current or former user of an implantable neural device. We acknowledge this as a limitation of the exercise and discuss this further in the Discussion section. Despite repeated efforts, we were unable to recruit a representative from the Australian National Health and Medical Research Council (NHMRC) or the Therapeutic Goods Administration (TGA). However, contacts from both organisations were consulted on policy matters during the development of provisional recommendations and expressed interest in the study's findings.

Other factors considered in panel selection were gender balance, direct scholarly engagement with post-trial responsibility, and panellists' academic or professional standing in the field. It was also important that panellists were broadly familiar with state and federal Australian research policies and health regulations. In general terms, the Australian federal government regulates areas with national scope such as medicines, medical devices, data protection, and the use of "unapproved" therapeutic goods, whereas Australian states and territories are primarily responsible for health service delivery including the funding of public hospitals. To this end it was important that our panel have representation from a number of Australian states and territories (Table 1).

### Workshops

In preparation for the first workshop the core team sorted ethical issues on post-trial responsibility into five themes. These issues were identified via an unpublished literature review and empirical studies by our group [28]. These five themes were: respect for persons, harms and benefits of research participation, responsibilities for continued support, access to research and continued support, and governance and innovation. Each theme was comprised of a set of ethical issues and ethical risk factors. We followed Drolet and colleagues in defining "ethical issue" as "any situation that may compromise, in whole or in part, the respect of at least one moral value that is considered socially legitimate and should thus be respected" [45]. We defined "ethical risk factor" as "a contextual factor that increases the likelihood of an ethical harm occurring, or changes its manifestation in some way" (e.g., the regulatory status of an investigational device in a jurisdiction) [46].

The objective of the first workshop discussion was to identify ethical issues and risk factors relevant to the Australian context by drawing from the five ethical themes. Panellists were divided into breakout groups facilitated by a moderator from the core team. First, the moderators presented and described *general* ethical issues and risk factors relevant to post-trial responsibility from each of the five themes. In the second step, panellists were asked to consider [1] whether, and to what extent, these general post-trial ethical issues constituted genuine concerns in the Australian context, and [2] whether there were any Australia-specific risk factors that might heighten their likelihood or severity or alter how they might manifest. In the final part of the workshop, panellists were invited to suggest ways to address specific ethical issues and risk factors in the Australian context.

The objective of the second workshop was to solicit feedback on a provisional set of recommendations. These provisional recommendations were developed from workshop 1 discussions and a review of relevant Australian state and federal regulations, national research ethics guidance, and international good clinical practice (GCP) standards. During the second workshop, panellists were invited to evaluate each recommendation according to ethical acceptability (i.e., the strength and targets of normative prescriptions), impact and desirability in the Australian context, and potential barriers to and consequences of implementation. Provisional recommendations were then revised in light of these workshop discussions ahead of the final survey.

### Consensus

After revising the provisional recommendations, a final consensus survey was completed by panellists. Panellists were again asked to evaluate each provisional recommendation for its ethical acceptability, impact and desirability in the Australian context, as well as the level of coherence between the recommendation summary and supporting rationale and explanation. Throughout the survey panellists were provided with relevant background on existing professional guidelines or regulations when the core team deemed them critical for evaluating the recommendation's feasibility in the Australian context. Consistent with the RAND/UCLA approach, the final survey allowed panellists to anonymously vote on each recommendation. Panellists were given the option of accepting the recommendation, accepting with minor amendments, or rejecting it and providing reasons for the rejection. Panellists also gave a rating of the importance of each recommendation for addressing post-trial ethical issues and risk factors in the Australian context.

Though not strictly a definition of consensus, we adopted an 80% acceptance threshold for consensus. This is consistent with other Delphi-style policy consensus studies in this area of the health sciences [47]. Correspondence with panellists during manuscript preparation was allowed for minor refinements to the recommendations without substantially altering their strength or intended targets.

## Results

### Summary of recommendations and consensus findings

The workshops and survey yielded a final set of 11 recommendations (Table 2). Twelve provisional

**Table 2** Summary of recommendations with panel consensus and importance ratings

| Recommendation | Consensus score after survey (% voted to "keep") | Median importance rating 1–5 (interquartile range) |
|---|---|---|
| 1. Participants must be fully informed of plans for post-trial arrangements during informed consent processes. | 100% | 5 (0) |
| 2. Supported approaches must be employed during informed consent processes to ensure plans for post-trial arrangements are communicated to participants according to their communication needs and capacities. | 100% | 4 (1) |
| 3. With participant consent, their families, carers and clinicians should be engaged throughout the trial wherever appropriate, as key parties impacting post-trial care. | 93% | 4 (0) |
| 4. Design of post-trial arrangements should be informed by those with lived experience of the condition or intervention, as well as their clinicians, family and carers, with participants' hopes and expectations about their post-trial device-related healthcare and quality of life explored and ascertained during consent and throughout the trial. | 88% | 4 (1) |
| 5. Study design and ethical review processes should identify assess for and mitigate risks of harm, discomfort, and adversity from the discontinuation of clinical development of devices. | 100% | 5 (1) |
| 6. Study design and ethical review processes should identify, assess for and mitigate risks of harm, discomfort, and adversity as a result of how participants are discharged from the trial or are transitioned into post-trial care. | 100% | 5 (1) |
| 7. Study design and ethical review processes should take into account how post-trial device-related support will be managed after the trial ends, and by whom. | 100% | 4 (1) |
| 8. Barriers to prospective participants accessing clinical trials and post-trial support should be identified and addressed. | 93% | 4 (1) |
| 9. Trial insurance and compensation agreements should stipulate whether and what post-trial participation-related harms are covered. This must be discussed with participants during informed consent, and investigators should be prepared to explain it or assist participants with finding answers to questions outside their competency. | 100% | 5 (1) |
| 10. Reform to medical device and clinical trial regulation should consider post-trial risks of participant harm, discomfort, and adversity. Regulators should be prepared to work with commercial and non-commercial device developers in addressing post-trial challenges. | 100% | 5 (1) |
| 11. Specific ethical guidelines and a framework of responsibility should be developed to inform the design, implementation and ethical review of post-trial arrangements. | 100% | 4 (1) |

recommendations were drafted ahead of the second workshop. Two underwent significant amendments prior to the final survey, and one recommendation did not progress after its ethical appropriateness was reconsidered in light of an improved understanding of Australian medical device regulation. Of the 24 panellists who attended the first workshop, six panellists did not complete the final survey. The core team (NH, AC, JG) also did not vote in the final survey, as they were directly involved in drafting the provisional recommendations. Accordingly, the consensus data reflect the views of 14 eligible panellists who completed the final survey (83% response rate).

None of the 11 provisional recommendations in the final survey fell below the 80% acceptance threshold. All recommendations underwent minor amendments in response to survey feedback. Eight recommendations received only "keep" votes from all survey respondents, whereas three (Recommendation 3, 4 and 8) received some votes to "discard". Panellists who had voted to discard certain recommendations worked with the core team to make minor amendments until they were satisfied. Recommendations in their final form were then reviewed and approved by panel members who co-authored the manuscript. All recommendations also achieved a median importance rating of 4 ('Very important') or above on our 5-point importance scale.

Below we present the 11 recommendations and their rationales. It is worth iterating that workshop discussions were carried out on an understanding that the current Australian institutional, regulatory, and funding environment should remain roughly as it is; they were developed to be practically workable within these structures. To this end, we applied a set of criteria to guide their design, ensuring consistency in formatting and in how prescriptive statements were supported by evidence and assigned to responsible parties (Table 3).

Where possible, parties responsible for meeting certain stated normative requirements (e.g., X should be done, Y must not be done) were explicitly referenced. New responsibilities were distinguished from those already required by ethical guidelines and professional standards. We have used several terms to qualify the normative force of each recommendation. Where national research ethics guidance, regulations, or laws prescribe a standard practice, we often use "it is required" descriptively to refer to the relevant governance in Australia. We use "should" to recommend changes in practice that may not yet be

**Table 3** Relevant standards and guidelines for clinical investigations of medical devices in Australia

| Title of document | Abbreviation | Form of governance | Description |
|---|---|---|---|
| Therapeutic Goods (Medical Devices) Regulations 2002 | TG Act | Federal legislation | The Therapeutic Goods (Medical Devices) Regulations 2002 establish the detailed regulatory requirements for the classification, conformity assessment, and ongoing monitoring of medical devices in Australia, specifying the procedures and evidentiary standards that devices must meet to be included in the Australian Register of Therapeutic Goods and remain compliant throughout their lifecycle. |
| The National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (2025)* | NS | National research ethics guidance | Australia's key research ethics guidelines that sets out principles and requirements to ensure human research is conducted ethically, responsibly, and with respect for participants. |
| NHMRC Participant Information Sheet/Consent Form Template for Interventional Studies (2025) | PICF | National research ethics guidance | Template document that helps researchers clearly explain study procedures, risks, and rights, and obtain informed consent from participants in clinical or other interventional research. |
| International Organisation for Standardisation (ISO) 14,155 – Clinical Investigation of Medical Devices for Human Subjects (2020)** | ISO 14155 | International standard | Outlines good clinical practice requirements for the design, conduct, recording, and reporting of medical device trials in human participants to protect their safety and ensure reliable data. |

*The latest NHMRC guidance was published in 2025 and referenced in this article, but this guidance does not come into effect in Australia until 2026

**As a practical note, because these guidelines are firewalled and not universally accessible, many researchers rely on adapted interpretations of ICH-GCP guidance

reflected in standard practice in Australia, and "must" to signal areas where a practice is already enshrined in ethical or professional governance but requires strengthening or clearer specification of how it should be implemented.

Where there was dissensus about a recommendation, even among those who voted in the survey to 'keep' it (e.g., "keep, with revisions"), these areas of discussion were explored in the recommendation description. For recommendations where there remained disagreement amongst panel members, these are also discussed. For Recommendations 1 and 8 we present supporting figures that propose how the recommendation could be implemented in the Australian context.

## Recommendations

### *Recommendation 1: Participants must be fully informed of plans for post-trial arrangements during informed consent processes*

Informed consent processes must include information about the purpose of the trial, the intervention, the study schedule, and the risks and potential burdens of participation. Trials of implantable neural devices often last several years, and changes in the participants' lifestyle or health status can occur during this time. Eligible participants often have progressive conditions and experience comorbidities that require ongoing lifestyle and healthcare adjustments.

When post-trial arrangements are discussed during the informed consent process, investigators must ensure that information about post-trial arrangements is fully disclosed, communicated clearly and transparently, and that participants and their families or support persons are given a genuine opportunity to consider these arrangements.[1] Participants should also be encouraged to involve their primary treating clinician/s, considering the potential impact on their current treatment and post-trial care requirements. There was broad agreement across our multidisciplinary panel that "fully" informing participants means providing them with as clear a view as possible of what to expect regarding their options for continued use of the device post-trial. However, there remained some disagreement about which specific kinds of information in an implantable neural device trial must be disclosed to "fully" inform participants, and on whether a subjective or objective standard of informed consent should apply.

Panellists did however agree that disclosure of post-trial information should address which kinds of care provided during the trial will continue to be available after

[1] Some information about reimbursements for approved medical devices may be publicly available through the Australian Register of Therapeutic Goods (ARTG), an online database maintained by the TGA that records therapeutic goods approved for supply in Australia and provides details about their regulatory status, safety, and intended use.

the trial, whether investigators, trial sponsors, or device manufacturers will be providing this support, and what responsibilities participants will have for their own continued care. Participants must be informed of whether device removal is planned as part of the trial protocol. If not, investigators must explain the conditions that might lead them to recommend device removal, including if and when the device can be fully or partially removed, and whether and for how long removal procedures will be funded by the trial. If participants are expected to have the option of continuing to use the device after the trial, they should be informed of the nature of follow-up procedures for maintenance and repair, and which elements of clinical care and technical support will be continued after the trial or will not be accessible to them outside the trial. Investigators should clearly delineate between elements of post-trial care that are accessible as approved, reimbursable healthcare services, and those that are 'unapproved' and only accessible via enrolment in a new trial or a special access scheme.

There can be lengthy delays between trial conclusion, regulatory approval, and reimbursement. It is important that participants are informed of relevant developments in the regulatory status of the trial device or changes in the funding of the trial or commercial strategy for the translation of the device[2]. These updates could influence participants' prospects for continued use and their willingness to continue participating. If the trial device is in an advanced stage of development, participants should be reasonably informed of timelines for the device's regulatory approval and commercialisation to enable them to make necessary preparations for their continued use of the device. In early-stage trials of investigational devices, it can be helpful to reduce the risk of therapeutic misconception (i.e., misconstruing research as clinical care) by emphasising that the purpose of the trial is to assess safety and tolerability, not to provide therapeutic benefit (see Recommendation 2 for more on supporting participant understanding) (Horng and Grady, 2003).

Panellists in our workshops acknowledged that current guidelines and standards already require disclosure of post-trial arrangements during consent. In Australia, national human research ethics guidance requires investigators to disclose (in oral and written form) information about the trial in a form and language participants can understand, and to inform participants throughout the trial of relevant developments that could influence their decision to continue participation[3]. There was agreement amongst our panel that these guidelines and standards could do more to assist investigators in knowing what must be explained, and how the longevity and associated surgical procedures for devices informs what should be emphasised in disclosure. Implantable devices that require surgical removal or may be intended to be lifelong raise disclosure considerations that should be given greater emphasis in national ethics guidance documents to assist investigators in designing ethical post-trial care arrangements and conducting informed consent processes (see Fig. 1).

#### *Recommendation 2: Supported approaches must be employed during informed consent processes to ensure plans for post-trial arrangements are communicated to participants according to their communication needs and capacities*

Participation in a trial of an implantable neural device often brings novel experiences or situations, or levels or kinds of risk, that are unfamiliar or unknown at the time of trial consent, and as such can be challenging to comprehend. Some of these experiences, situations, or risks related to trial participation may arise only after the trial has ended (e.g., surgical device removal) [48]. Setting expectations about these situations and experiences so that potential participants are able to appropriately consider them can be challenging under normal circumstances. This becomes even more difficult when prospective participants are desperately looking to improve their health condition with few or no other treatment options, or when cognitive impairments related to their health condition make it harder for them to understand information and weigh their options [49, 50].

In Australia, it is best clinical practice to employ supported approaches during informed consent. Funders, regulators, and Human Research Ethics Committees (HRECs) must consider the need for informed consent supports during the design stage of research. National human ethics guidance requires that information be presented in ways suitable to each participant[4] and that any supports be appropriate to each participant's needs and circumstances "taking into account the nature of the research and how these factors may interact".[5] Several encounters are usually required for consent to be obtained.

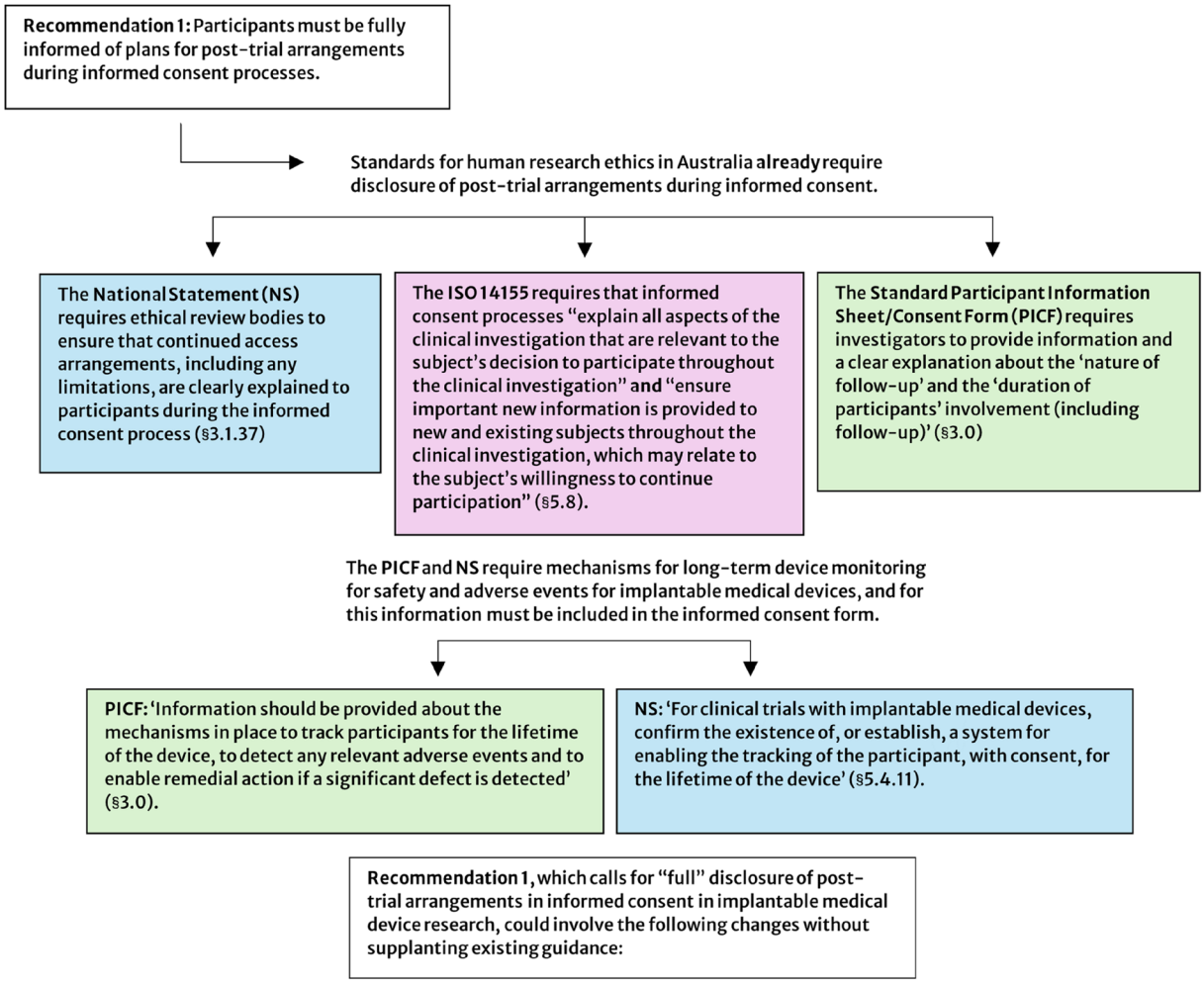
Deciding to participate in an implantable device trial requires participants to imagine receiving an investigational, potentially lifelong implant with significant and uncertain risks. Investigators and HRECs must consider whether and how to support them to comprehend the long-term implications of trial participation. Consultation with relevant patient and participant reference groups is necessary during the design and funding stages to ensure appropriate communication and informational

[2] NS, 2025, § 2.2.8.

[3] NS, 2025, § 3.1.37.

[4] NS, 2025, § 5.3.6.

[5] NS, 2025, § 4.2.1.




The PICF (§3.0) and NS (§5.4.11) require communication of plans for **safety** and **monitoring**. These guidance documents should emphasise transparency from investigators and sponsors about their capacities to provide continuing support for implantable devices in the long-term as a way of empowering participants in their decision to undergo a procedure with potentially lifelong implications. Careful expectation-setting about the clinical and technical requirements of post-trial continued use, and which aspects of care will be available and for how long, may be decisive in whether participants choose to enrol.

The continued use of implantable neural devices presents unique ethical considerations for post-trial continued use. National guidelines should recognise informed consent in **active implantable medical device research** as requiring special attention to the long-term implications of participation. Investigational medical devices may require surgical removal many years later, raising questions about responsibility if the original team is no longer available. Some are intended to remain implanted for the lifetime of the device, others are permanently implantable devices. Post-trial care must be realistic, as new treatments may not become available if indefinite support or support not feasible from the institution or sponsor perspective is mandated. A narrow focus on device safety and monitoring for adverse events do not capture the complex follow-up involved in implantable system trials (e.g., repeat surgeries, device maintenance), which may tie participants to the device company or investigator for many years.

The NS and ISO 14155 require that post-trial arrangements be disclosed to participants, but they do not **specify what information** should be communicated. Both documents draw on the Declaration of Helsinki, but it too does not set out such detail (see DoH §34). A model for how this information could be included in the NS is the 2016 CIOMS guidance from the WHO. These guidelines require that participants be informed about 'how the transition to care after research is arranged, to what extent they will be able to receive beneficial study interventions post-trial, and whether they will be expected to pay for them' (Appendix 2). They also call for clear 'provision for continued access to study interventions that have demonstrated significant benefit, indicating its modalities, the parties involved in continued care, the organisation responsible for paying for it, and the duration of continued access'.

**Fig. 1** Implementation of first recommendation on disclosure of post-trial arrangements to participants during informed consent in Australia

supports are available to participants who need them (e.g., translating services, short videos, illustrations and written material with easy readability).[6] Investigators, with ethical approval and the aid of the trial institution, should also explore opportunities to allow participants to meet with relevant consumer representatives, such as former trial participants or patients who have previously used similar devices. Alternatively, approved videos of individuals from these groups describing their experiences could be utilised as part of the consent process, with caution required to prevent them becoming testimonials. These conversations may be critical in supporting participants to set expectations, consider the long-term implications of trial participation, and ultimately decide whether an investigational implantable device is the right choice for them.

***Recommendation 3: With participant consent, their families, carers and clinicians should be engaged throughout the trial wherever appropriate, as key parties impacting post-trial care***

Families and carers are often involved in participants' care during the trial, follow-up studies, and beyond. It is standard in Australian research to consult families and carers, wherever possible, as key knowledge-holders in a manner appropriate to each participant's circumstances.[7] During the trial, families, carers and clinicians can provide valuable insights into the device's effects on participants' symptoms and quality of life. Families and carers may play an important role in helping participants adjust to the intervention, and they may also be impacted as participants respond to the intervention. Trial participation can reshape family dynamics, relieving caregiving burdens or enabling new relational roles [51–53].

Given that some devices are intended to be implanted for the lifetime of the device, investigators should consider not only whether participants have adequate family, carer and clinician support to meet the demands of the study, but also the longevity (or continuation of) that support beyond the end of the trial. Investigators should be prepared to identify and allow for changes in participants' care arrangements, particularly when foreseeable changes are raised by the participant during recruitment (e.g., the declining capacity of an older family member to provide care or make decisions, change in General Practitioner or specialist). Investigators should be cautious that making robust family or carer support an inclusion criterion could exclude otherwise eligible individuals who lack such support, potentially disproportionately affecting marginalised or socially isolated groups. While some participants will depend on caregivers or relatives for ongoing support, others may not require their families or carer to be involved during the trial.

Investigators should also carefully consider the potential for family and carer involvement when designing the trial and informed consent processes. Although involved and better-informed families and carers will be able to better identify post-trial needs and support post-trial care, sharing information with them must be explicitly consented to by the participant. If the participant agrees to involve family members and carers in decision making, investigator teams should be prepared to account for how factors such as complex relational dynamics and cultural and linguistic diversity may shape informational needs and the nature of decision-making about the long-term implications of participation. If investigators intend to gather information from families and carers for the purposes of the trial or post-trial device use, formal and separate consent must be obtained. If investigators believe that the nature of the intervention or target condition may have an effect on participants' capacity to consent to participate in or withdraw from the trial, this must be reflected in the trial design and approved by the HREC (e.g., Advanced Care Directives, nomination of Medical Treatment Decision Makers)(see Recommendation 4 for more on the involvement of families and carers).

Unlike family and carer involvement, which must be carefully navigated according to each participant's individual circumstances, it is essential that participants' primary treating clinicians are actively engaged and consulted throughout the trial, rather than just at the beginning.[8] Establishing connections with referring clinicians, including the sharing of participants' trial-related health information at the end of the trial, is critical to ensuring continuity of care. During the trial, the clinician may need to be informed by the research team of adverse events or changes to the participant's intervention. In some circumstances, participants' referring clinicians could be assisted to cultivate certain clinical and technical skills – commensurate with their training – to take on aspects of participants' ongoing care related to the trial intervention as part of a shared care arrangement. Negotiations may need to occur regarding which aspects of care sit with whom, depending on the participant's available clinical team. At a minimum, the primary clinician will be caring for the participant post-trial and will need to be aware of outcomes and future plans for the intervention (see also Recommendation 7).

***Recommendation 4: Design of post-trial arrangements should be informed by those with lived experience of the condition or intervention, as well as their clinicians, family and carers, with participants' hopes and expectations about their post-trial device-related healthcare and quality of life explored and ascertained during consent and throughout the trial***

It is routine to discuss participants' hopes and expectations about the nature and purpose of the research

[6] NS, 2025, § 4.5.33.

[7] NS, 2025, § 4.5.29; PICF § 1.

[8] NS, § 2.2.6; PICF, § 3.

during informed consent. This is primarily to ensure participants appreciate the difference between a research trial and medical treatment; while participants may benefit from their participation, the purpose of a clinical trial is to investigate the clinical impact of an intervention, including its safety and tolerability and/or efficacy. It is important to discuss hopes and expectations to ensure participants understand the scope and boundaries of investigator roles and expected outcomes of the trial (see also Recommendation 7).

However, participants will often hold certain hopes and expectations *about* their participation that do not strictly relate to the *purpose* of the trial. For example, participants may have specific 'post-trial' hopes and expectations about what trial participation will mean for their long-term healthcare and quality of life. Participants are likely to have had experiences with the standard of care, or with healthcare services more broadly, that have shaped their expectations or hopes with regard to continued use of the device after the trial has ended, access to the trial site, or ongoing relationships with the investigator team after the trial ends.

Realistic and appropriate post-trial care and support options should be discussed prior to protocol design. Families, carers and clinicians should be consulted prior to the design of the trial, and ideally co-design the trial with researchers and those with lived experience of the condition, including by identifying what post-trial care needs there may be, what flexibility may be required and what current resources there are for care. While study designs need not be configured to meet the post-trial hopes and expectations of individual participants, they should accommodate, or at least not needlessly obstruct, participants from pursuing post-trial goals – especially when these accommodations are relatively simple, not resource intensive, or can be incorporated in initial trial funding proposals (see Recommendation 6 for more on the configuration of post-trial arrangements).

It will often not be possible to canvass all of participants' hopes and expectations during recruitment. As participants' health, lifestyle, or preferences evolve during the trial – particularly in response to how well they benefit from the therapy – their goals for life after the trial may also change. Participants' post-trial hopes, expectations, concerns, and fears should continuously be explored and ascertained, and should be used to inform future trial co-design. For example, if previous trials of similar devices have found that surgically removing devices caused participants psychological harm or distress, HRECs should consider requiring provisions for psychological and support services beyond the participant's involvement in the trial.

Importantly, careful consideration should be given to who is most appropriate and qualified to hold discussions about post-trial hopes and expectations. Discussions of participants hopes and expectations about their post-trial healthcare arrangements should only be with their primary treating clinicians as this is within their expertise and the scope of their role. Engaging in healthcare-related discussions with an investigator who is not clinically trained may introduce risks, particularly if they are not equipped to provide appropriate clinical advice or do not have all the information about the participant's health or health care. However, discussions of hopes and expectations limited in scope to the device and post-trial support (e.g., programming and calibration, software and hardware updates, repeat medical procedures) may be realistically explored by clinical trial personnel most knowledgeable about the likely outcomes and ongoing device-specific care to be offered. In some instances, there may be ambiguity as to whether certain post-trial hopes and expectations raised by participant are *clinical* in nature. Investigators should judge whether post-trial support issues fall within their remit, should be referred to the participant's primary healthcare provider, or require coordinated input to determine appropriate post-trial arrangements.

#### *Recommendation 5: Study design and ethical review processes should identify, assess for and mitigate risks of harm, discomfort, and adversity from the discontinuation of clinical development of devices*

Most trials fail to deliver new therapeutics. There are numerous scenarios that could lead to the clinical development of an implantable neural device being discontinued. A clinical trial may be terminated early due to safety concerns. Funding may not be obtained for investigator-initiated device development to progress to the next stage towards commercialisation. If clinical endpoints are not met, an industry trial sponsor may decide not to progress to the next stage of clinical development. A sponsor may change its commercial strategy and decide to shelve the product after the trial, or wind down operations entirely, if a device is not forecast to succeed on the market.

Discontinuing the development of an implantable device can expose participants to risks of harm, discomfort, and adversity. Risks to participants that arise as a consequence of trial termination or later discontinuation of device development should be addressed during HREC review. HRECs should, as part of the review process, work with trial investigators and sponsors to identify and assess risks of discontinuation. A pragmatic way to support this in Australia would be to amend the National Human Research Ethics Application to specifically ask about the potential risk of an implantable neural device being discontinued during the trial, along with corresponding mitigation and management strategies [54].

HRECs should require trial risk management plans to include strategies to minimise and manage risks if the

trial is discontinued. As a matter of institutional governance, legal agreements signed between parties should, where possible, establish lines of accountability for risk mitigation. Clear lines of accountability should be identifiable to, and form part of, the HREC review process. Commitments from sponsors and device manufacturers will need to be secured beforehand.

In Australia, if a sponsor terminates a trial early the sponsor is required to notify all relevant parties without delay.[9] After notifications of early trial termination have been made, Australian NHMRC guidance recommends that the HREC convenes to review processes for "informing participants" and arrangements for "continued care and follow-up".[10] With respect to these Australian standards for trial termination, investigators should briefly engage and consult with participants, families, and caregivers to gather updated hopes and expectations at this point in time for the specific circumstances so that HRECs can take these perspectives into consideration when deciding on the most acceptable and appropriate arrangements for continued care.

#### *Recommendation 6: Study design and ethical review processes should identify, assess for and mitigate risks of harm, discomfort, and adversity as a result of how participants are discharged from the trial or are transitioned into post-trial care*

Post-trial arrangements are often configured depending on the nature of the intervention and the stage of the trial. For certain implantable devices with prior regulatory approvals, participants may have the option of continuing to use the device *off-label* with occasional visits to the trial site for device maintenance. Other trials may write device removal into the trial protocol, for example if it is a first-in-human investigator-initiated trial where longer term safety and device support are less clear. In trials of permanently implantable devices, it may not be safe or feasible to remove the implant at the end of the study, even if it is a first-in-human trial.

This recommendation concerns risks to participants that may arise after the end of a trial because of the specific configuration of trial discharge procedures or follow-up arrangements. Our multidisciplinary panel accepted that planning for follow-up and continued care is established good clinical practice in Australia. Clinical trials are required to implement "appropriate" procedures for monitoring safety and tolerability, and for reporting and providing medical care for adverse events during the trial [56]. Relevant GCP standards for medical device trials lay out what is appropriate for safety and monitoring for adverse events.[11]

However, what constitutes 'appropriate' follow-up – beyond the cadence of visits to the trial site for safety monitoring – is less clear for implantable neural devices. Loss of access to the device or device-related support, or changes in how a participant is able to use the device, may cause harms that are neither well understood nor simple to monitor. Evidence suggests that when participants exit these trials they face potential psychological and social harms, as well as discomforts and burdens, that are more subtle and difficult to detect than the physical risks of continued device implantation or removal [24, 26]. For example, during the trial, participants attend regular study visits over several years, building close, collaborative, and empowering relationships with the research team [53, 57, 58]. By contrast, post-trial follow-up may involve few or no site visits, with only ad hoc communication about safety or data collection over a limited period. Such arrangements may be appropriate for the purposes of safety and tolerability monitoring, but they can overlook potential feelings of isolation, loss of connection, and diminished sense of meaning that participants may experience after the trial has ended. Similarly, participants in some early first-in-human studies may be required by the protocol to undergo surgical device removal at the end of the trial [17]. This has the potential to lead to distress or unwelcome changes in personality, identity, or sense of agency, particularly if the device had been experienced as effective or empowering during the trial [26].

Investigators and sponsors should work with HRECs to identify and assess more subtle risks of psychological and social harm, distress, discomfort, burden and vulnerability that may arise as participants' transition out of the trial or at the conclusion of the follow-up period. Ethics approval of arrangements for follow-up and continued use must consider whether there are appropriate risk minimisation, mitigation and management procedures in place. Importantly, if the trial protocol involves optional surgical removal of the device at its conclusion, or if device removal is clinically recommended for other reasons by investigators, HRECs must ensure that participants are not subjected to undue pressure to undergo surgical removal procedures [59].

#### *Recommendation 7: Study design and ethical review processes should take into account how post-trial device-related support will be managed after the trial ends, and by whom*

Study design and ethical review processes should take into account how post-trial device-related suppor

[9] ISO 14,155, § 1; 8.2.1. Sponsors must also promptly notify the TGA in accordance with the TGA's scheme for the investigation of "unapproved" therapeutic goods (TGA, [55]).

[10] NHMRC, 'Safety monitoring and reporting in clinical trials involving therapeutic goods', 2016, p.10.

[11] ISO 14,155, § 6.7, 10.7.

Device maintenance and care for participants with implanted devices often requires ongoing specialised clinical and technical expertise. After the trial, participants may need to return to trial investigators or the sponsor for kinds of care and support outside the clinical competencies of their primary treating physician (e.g., device repair and maintenance). If continued use in an option for participants, it is current best practice for investigators to contact and even seek approval from a participant's personal physician at the start of the trial, so that personal physicians would have the information and resources needed to manage ongoing care after the trial.[12]

If elements of post-trial care cannot be carried out by the participants' primary care provider after the trial, certain members of the research team with the requisite specialist or technical skills may need to take on ongoing support responsibilities for trial participants. For example, clinical psychiatrists or neurologists involved as investigators in a DBS trial may assume responsibility for device calibration, while bioengineers in a BCI trial may be the only ones with the expertise to perform programming and software updates.

For participants who continue to use a device after the trial has ended, reliance on a lone or small number of trial investigators poses a risk to their ongoing care if these individuals become unavailable due to retirement, relocation, or other reasons. For these trial investigators with exclusive clinical or technical expertise to manage the device - many of whom may be passionate about seeing these participants continue to benefit - there may be no reimbursement for ongoing device-related procedures if these devices are not yet covered by health insurance, and the time commitment involved may limit the researchers' capacity for other clinical research projects or provision of clinical care to other patients. Academic clinical researchers may not obtain sustainable funding for ongoing research programs and may therefore no longer be able to offer support to previous participants. There may also be issues with liability and insurance coverage for these experts if they provide support to participants when they are no longer covered by clinical trial insurance, which may then lead to reluctance to provide any post-trial support.

HREC review processes should require that investigators consider both the feasibility of research team members providing ongoing device maintenance for participants and the risk of technological obsolescence, which could compromise long-term usability and participant safety. Attention should be given to device software and hardware maintenance responsibilities that are likely to accumulate, and which members of the research team are likely to assume these responsibilities. These discussions between HRECs and investigators should occur during initial ethical review of the clinical investigation plan, rather than being deferred until ethical review of follow-up extension studies, or until participants have already completed the trial. HRECs should work with investigators, sponsors, and the trial institution to consider what supports (e.g., financial, technical, legal) can be made available to help research team members manage long-term device support responsibilities, and who will assume these responsibilities if the originally responsible persons become unavailable (see Recommendation 10).

#### *Recommendation 8: Barriers to prospective participants accessing clinical trials and post-trial support should be identified and addressed*

Socioeconomic and geographic barriers put many approved implantable neural devices (e.g., DBS) out of reach for many who need them [60]. These barriers also prevent many eligible individuals with neurological and psychiatric disorders from participating in trials. For example, a potential participant may be excluded from a trial due to concerns that they will be unable to meet study demands, or that valid informed consent will be difficult to obtain (e.g., due to linguistic, cultural, or ethnic differences; fluctuating or reduced decisional capacity). Many individuals may not participate simply because they never have the opportunity to hear about the trial (e.g., due to geographic isolation or socioeconomic challenges).

Most of the time, these barriers are construed and addressed in terms of how they prevent otherwise eligible patients from participating. But barriers to accessing research should also be construed in terms of the disproportionate effects on participants' ability to continue accessing interventions *after* the trial. Some eligible individuals may be able to participate in a trial but will be disproportionately affected by barriers to continued use after the initial trial ends. Anticipating how their continued use will be impacted by barriers post-trial, some prospective participants may elect not to enrol in the trial on this basis. From the recruitment side, there is a risk that concerns about loss of participants to follow-up - and the implications for long-term monitoring and data collection - may tilt recruitment towards participants from more urban and economically privileged areas.

Investigators, HRECs and trial sponsors should work to identify and address barriers to follow-up and continued care. How identified barriers are addressed will depend on the context of the study and resources of the primary funding source. For example, in a late-stage clinical trial of a device, or where a device is approved for use in other conditions, investigators and sponsors should strive to ensure that participants' socio-economic or geographic

[12] ISO 14,555 § 5.8.4.

circumstances do not disproportionately impact post-trial use of the device. Doing so could involve enquiring as to whether disadvantaged participants are eligible for special access or financial support programs offered by the device manufacturer, relevant charitable organisations, or benefit schemes within the healthcare system.

Although most of the personal cost of continued use paid by past participants will be associated with specialist healthcare services and device maintenance, sponsors, investigators, and HRECs should also consider how the costs of travel (and in some cases, accommodation) for regular outpatient visits can act as a barrier. The level of reimbursement for travel and accommodation deemed acceptable during the trial may disproportionately affect participants who are geographically isolated or socio-economically challenged once the trial concludes. Decisions about reimbursement should recognise that while excessive payment may unduly influence participation, this issue is often overblown resulting in insufficient payment and can stand as a barrier to ongoing access (see Fig. 2 for examples).

#### *Recommendation 9: Trial insurance and compensation agreements should stipulate whether and what post-trial participation-related harms are covered. This must be discussed with participants during informed consent, and investigators should be prepared to explain it or assist participants with finding answers to questions outside their competency*

The insurance landscape surrounding clinical trials is notably complex. Fundamentally, trial insurance functions to provide financial and operational protection against liability claims brought on by adverse or unforeseen events during the trial. Sponsors running medical device trials in Australia use standard agreements that contain indemnity provisions requiring the sponsor to compensate participants for injuries or harms arising from their participation in the trial [61, 62].

However, the basis for compensating participants becomes uncertain if harms are not clearly trial-related or if they only arise once the trial has been closed and these governance agreements have expired. For participants who continue using devices after the end of the trial, participants in trials of devices with prior regulatory approvals may be able to rely on public health coverage or private insurance to cover costs of device-related injuries or harms. On the other hand, participants continuing to use devices that are 'unapproved' may lack coverage and protection after the trial ends despite facing ongoing and potentially serious risks related to the intervention.

Sponsors and trial institutions responsible for these trials, along with research governance officers, must explicitly ensure that their policies meet agreed standards for compensation. There should also be clear and explicit communication to participants of the types of harms covered and duration of coverage. Participants must have a genuine opportunity during informed consent to discuss the insurance protections available for device-related harms that may arise after the trial concludes. The existence and nature of these protections may be a critical factor in participants' decisions to enrol, especially in trials where participants are consenting to receive potentially lifelong or irreversible implantable devices.

Although investigators should not be expected (nor attempt to) fully explain legally dense indemnity and compensation agreements if outside their scope of competency, they should nonetheless be prepared to walk participants through the basic elements of these protections and entitlements and convey their significance in the context of the investigational device, or for the information to be provided in a way that is easily understandable. Crucial in this discussion is a disclosure of potential limitations of existing insurance protections once the trial ends. If participants have questions about compensation or insurance arrangements that investigators do not have the knowledge to answer accurately, investigators should promptly connect them with the trial designated person to address such queries.[13] Designated trial persons must be prepared to provide clear explanations regarding whether, and to what extent, device-related injuries and other harms will be covered after the trial ends.

Organisations responsible for drafting and updating Australian standard compensation and insurance agreements used across industry and investigator-led trials should ensure that these guidelines reflect the latest ethical and professional standards regarding participant wellbeing in medical device trials. These organisations should ensure that any compensation guidelines reflect the range of clinical trial sponsors, trial designs, and insurers.[14] Standard agreements must stipulate as clearly as possible whether, and to what extent, and for what duration, research-related harms, including psychological and social harms and distress due to the use of an investigational device, are covered after the trial has concluded.

#### *Recommendation 10: Reform to medical device and clinical trial regulation should consider post-trial risks of participant harm, discomfort and adversity. Regulators should be prepared to work with commercial and non-commercial device developers in addressing post-trial challenges*

National reforms to medical device regulation should consider post-trial harms specific to implantable

[13] PICF, § 17.

[14] The MTAA Compensation Guidelines have not been updated since 2010 (1st version). Various federal and state-level research governance documents direct clinical trial organisers to use Medical Technology Association of Australia (MTAA) compensation guidelines and standard governance templates. For example, the Victorian Department of Health's Research Governance Checklist and Ethics Checklist for clinical trials both refer to standard MTAA agreement templates.

**Recommendation 8:** Barriers to prospective participants accessing clinical trials and post-trial support should be identified and addressed.

Some geographic and socioeconomic barriers to accessing trial participation and ongoing support are unique to the specific to the regulatory context and participants' personal circumstances.

## Federal regulations

**The Australian Prostheses List (PL)** contains registered medical devices for which insurers must pay a benefit when a member has the relevant coverage (Private Health Insurance Act, 2007). The PL enables practitioners to choose the best available prostheses for privately insured patients without restrictions from health funds.

Some implantable neural devices are listed on the PL as they hold prior regulatory authorisations (e.g., DBS), even if they continue to be investigated in clinical trials for conditions that are not approved for.

Trial sponsors may have funding to cover devices and procedures only for duration of the trial. After the trial, if a privately insured individual continues using an investigational device outside the clinical trial, the participants' private insurance may be needed to cover the minimum benefit for hardware maintenance.

**Barrier to accessing continued support**

Many implantable devices require hardware maintenance and repair, and uses of approved devices in a research context may require more frequent maintenance procedures (e.g., DBS for certain psychiatric conditions).

Participants without private health insurance cannot access PL benefits for device replacements. They may instead need to obtain device hardware replacements (e.g., batteries) through the public health system. Accessing specialist services publicly can result in long wait times and uncertain availability.

The prospect of being unable to afford continued use of a device may discourage some individuals from participating in clinical trials in the first place.

## Interstate regulatory differences

In some Australian states and territories, psychosurgery is **prohibited.**

The New South Wales Mental Health Act 2007 (NSW, s.83) and the Northern Territory Mental Health and Related Services Act 1998 (NT, s.58) prohibit psychosurgery, including the use of neurosurgical devices (e.g., DBS) for psychiatric conditions.

Trial participants living in these states who receive investigational DBS for a psychiatric condition cannot legally access care for the use of this device, such as device calibration, lead adjustment, or surgical battery replacement (RANZCP, 2022)

**Barrier to accessing continued support**

If participants are eligible to enrol in a psychosurgical DBS trial in a state where the procedure is legal (e.g., Victoria or Queensland) but live in or later move to a jurisdiction where it is prohibited (e.g., NSW or NT), they would need to travel interstate to undergo the procedure and receive ongoing outpatient care.

During the trial, this typically involves sponsor-funded flights and accommodation for surgery, device calibration, and follow-up visits at the study site. However, once the trial concludes, or if funding does not extend into follow-up phases, participants may lose this financial support.

Without sponsor coverage, the costs of regular interstate travel could create substantial financial, logistical, and psychosocial burdens, leading to inequities in access compared to participants living in jurisdictions where the procedure is permitted.

## State regulations

The Victorian Patient Transport Assistance Scheme (VPTAS) subsidises travel and accommodation costs for Victorians who must travel **long distances** (>100km) to access specialist treatment.

The scheme **excludes** patients receiving specialist care for interventions received as part of clinical trials or experimental treatments.

**Barrier to accessing continued support**

In trials of implantable neural devices, participants are typically reimbursed for travel and accommodation costs during the primary trial period, but not for outpatient visits over follow-up extension studies, as the budget has typically been exhausted.

Because these follow-up visits are still considered part of a clinical trial (they are receiving care for an 'unapproved' therapy), participants may not be eligible for VPTAS support for travel related to device maintenance.

Those living long distances from the study site could face disproportionate financial burdens associated with travelling to the study site for care related to continued use without the support of this benefit scheme.

**Fig. 2** Examples of barriers to accessing clinical trials and post-trial support in implantable neural devices trials in Australia

medical device research [24]. In 2019, the Australian TGA launched 'An Action Plan for Medical Devices' as part of a broader government reform effort to improve the quality and transparency of clinical investigations of medical devices [63]. Some of these recent reforms have targeted oversight of higher-risk medical devices.

In implementing these reforms, consideration should be given to how trial organisers can be supported in managing the ongoing uncertainty around post-trial responsibilities, particularly in contexts where internal governance processes and current guidance are inadequate. Measures that increase scrutiny of medical device sponsors and improve long-term participant safety and wellbeing are welcome, but they should not impose an insurmountable burden on sponsors and investigators. For example, there was industry pushback against the TGA's commitment to review more devices under the more costly and extensive Clinical Trial Authorisation (CTA) pathway for clinical trial approval compared to the Clinical Trial Notification (CTN) pathway. An Australian industry consortium cautioned that higher costs and extended review times under the CTA scheme may reduce the number of first-in-human trials and subsequent studies conducted locally [64].

Regulatory bodies should explore mechanisms to support developers of implantable neural devices, especially investigator-initiated studies and start-up manufacturers, who may be disproportionately affected by the costs associated with providing post-trial support for users of irreversible or lifelong devices. For example, the CTA scheme is currently under review as of 2025. If it requires sponsors to provide a plan detailing how they will manage long-term implants as part of trial authorisation (as recommended in other jurisdictions[15]), regulatory bodies should explore options to support sponsors in doing so. One option to support and encourage innovation while providing realistic and appropriate participant protection would be to establish a central fund to assist investigators and sponsors with the ongoing costs of device maintenance and repair where no reimbursement is available within the public health system [16, 65].

#### *Recommendation 11: Specific ethical guidelines and a framework of responsibility should be developed to inform the design, implementation and ethical review of post-trial arrangements*

There is a growing emphasis on life-cycle based approaches to the assessment, development, and use of medical devices [66, 67]. This has been reflected in recent reforms that have enshrined clear responsibilities for device sponsors and manufacturers across the entire life span of devices. In Australia, recent reforms reflecting this life-cycle approach include the requirement (introduced in 2025) for device manufacturers to submit and maintain unique device identifiers for approved medical devices (UDIs) [68] and expanded post-market surveillance and adverse event reporting obligations [69].

For trials of implantable neural devices, the incorporation of life-cycle based approaches into local decision-making about post-trial responsibilities can be challenging. If it is accepted that a key aspect of HREC review is how an investigational implantable device will be used after the trial ends, then review processes must necessarily look ahead to later stages of the device lifecycle, particularly where the intervention is an implantable and potentially lifelong device. The question of which stakeholders *should* assume responsibility for post-trial support is complicated by the range of possible developmental trajectories the device may follow, and by the competitive commercial pressures of medical device research and development, which can render commitments to post-trial support unrealistic.

Current ethical guidance, good clinical practice standards, and even regulatory reforms that enshrine ongoing sponsor responsibilities do not provide clear guidance on what is required in these situations. For example, it is unclear how HRECs should factor into their decision-making the foreseeability that a foreign trial sponsor might leave the country or disengage with participants after collecting local data, potentially leaving participants with implanted investigational devices but without local support. Similarly, it is unclear how HRECs should take into account that trials of certain implantable neural device systems (e.g., BCIs) foster unusually close, collaborative relationships between researchers and participants. These questions are particularly challenging when devices are intended to remain implanted for the lifetime of the device or the participant.

There is a need for an adaptable international ethical framework of post-trial responsibility to inform decision-making about the appropriateness of post-trial arrangements. Ethical guidance that can be specified in cross-jurisdictional contexts is needed because HRECs must be able to provide clear rationales for decisions to approve a trial, approve an extension, or suspend a trial. Current ethical guidelines do not support researchers to effectively design ethical post-trial arrangements, let alone equip HRECs to justify concerns regarding the ethical adequacy of post-trial arrangements.

This ethical framework should satisfy at least three desiderata. First, it should be capable of being adapted to the specific research context, including the legal,

[15] For example, see recommendation 12 of the UK Regulatory Horizons Council report in 2022 'The regulation of neurotechnology': "As part of its plans to amend the UK Medical Devices Regulations to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance and vigilance system, the MHRA should consider requiring manufacturers to present a plan describing how they intend to manage long-term implants installed in patients, as part of their submission to Approved Bodies.

regulatory and healthcare systems in which the research is taking place. Second, it should identify critical decision points where responsibilities may shift between stakeholders and outline a continuum of acceptable arrangements in light of various contingencies and possible scenarios. Finally, this guidance should be reasonably sensitive to a breadth of clinical, trial, and device-related factors, including but not limited to, the device's mode of administration, risk classification, intended duration of use, context of use (e.g., visits to the site vs. in-home care), as well as the trial phase, and whether the device has prior regulatory approvals.

This guidance should be developed through an interdisciplinary consultation and collaboration process, and relevant aspects should be incorporated into national research ethical guidance and clinical trial governance.

## Discussion

Trials of implantable neural devices are increasing, with a number of neurotechnology companies preparing to launch large, multi-site, pivotal trials in the coming years. However, there is still considerable uncertainty over the post-trial responsibilities of trial stakeholders, and how these should be negotiated and communicated to participants throughout the trial. Existing guidance enshrined in international research ethics documents is inadequate in this area of medical device innovation. Meaningful progress will necessitate multi-disciplinary collaboration and attentiveness to how context shapes what is acceptable and feasible.

We outline 11 recommendations on post-trial responsibility. We designed these recommendations to be feasible and ethically desirable within current Australian governance and funding structures, and so some of the implementation groundwork has already been laid. As panellists reviewed provisional recommendations, they were prompted to consider the feasibility of each provisional recommendation in their evaluation of its desirability. Part of this consideration of feasibility required that panellists draw from an understanding of the general roles and responsibilities of key actors working in clinical research, and the general limits of what can be reasonably expected of individuals or organisations [70]. A key advantage of bringing together Australian multi-disciplinary experts, however, was that panellists were also able to assess the feasibility of recommendations in the Australian context, such as whether an ethically acceptable practice was already required under Australian governance frameworks, or whether a responsibility that might be appropriate elsewhere would be unnecessarily burdensome in the Australian setting.

We found that panellists most often voted against a recommendation when they disagreed about its feasibility in the Australian context. One form of disagreement came from panellists who felt that the post-trial responsibilities being proposed had already been represented in internal organisational policies or were routinely carried out in their area of professional practice. For example, one panel member's perspective was that large medical device companies had built many post-trial considerations into their standard operating procedures because they had the resources and translational experience to do so.

We were not surprised to discover differences in organisational or disciplinary preparedness for post-trial matters across our multidisciplinary panel. Implantable neural device research covers a variety of device types at different stages of development, regulatory approval, and integration into Australian clinical practice. It was, on the contrary, encouraging that some panellists reported their organisations or professions had already found ways to manage certain post-trial dilemmas to an acceptable standard, as this suggests implementation is feasible. Future empirical ethics work on this problem should also consider investigating local institutional policies and strategies that have been established to address post-trial issues. A recent attempt at this was published by Bassil & Jongsma (2025), who investigated the deliberations of Dutch HRECs on issues of post-trial responsibility using open-ended questions to explore explantation decisions, post-trial care responsibilities, and consideration of risks of psychological harms.

We did not, however, regard reported successes in managing of post-trial tensions as sufficient reason to discard certain recommendations outright, nor as necessarily weakening their ethical appropriateness. It is promising that some Australian organisations and professional sub-disciplines perform better in particular areas of post-trial responsibility; however, this does not obviate the need for broader action and implementation in the Australian context. Grant-funded investigators new to clinical trials, and start-ups preparing their first studies, should not be left to navigate these issues without clear ethical guidance. A crucial step as the field continues to develop such guidance (see Recommendation 11) is recognising post-trial responsibility as a bona fide research ethics issue; hitherto, there has been a tendency to frame post-trial responsibility as a fragmented moral problem dispersed across the domains of law, corporate governance, and clinical care. These recommendations show how post-trial responsibilities can be embedded in research governance. They also suggest that, while few areas raise wholly unique ethical issues, some areas of innovation – such as implantable neural devices – require guidance tailored to their distinctive ethical, practical and regulatory challenges.

These recommendations and the process used to develop them are not without limitations. Not all panellists who participated in the workshops completed

the final survey (3 panellists and the core team members, who were not eligible to vote, did not complete the survey). While the response rate of 83% among eligible participants was high for a Delphi study [39], we acknowledge that this may limit the generalisability of the findings to Australian stakeholders and actors working in this innovation area and may increase the influence of individual perspectives.

Though our multidisciplinary group included several lived experience and disability advocates, to our knowledge none of the panellists were current or former users of implantable neural devices. Just as it is essential to involve potential participants, co-researchers, and community representatives in study design and planning, it is crucial to engage them when developing ethical recommendations, so these reflect participants' priorities, values, and needs. Local lived experience community and consumers will be critical for informing the research governance in Australia. Consultation with local consumer groups in the development of ethical guidance should include those who have used or are using commercially available implants, rather than only those with general research participation experience as their lived experience will be essential in determining post-trial care needs. As the recommendations in this study bear out, post-trial issues are context-sensitive, and ethical risks and mitigation strategies in Australia may not translate directly to another.

## Conclusion

This study provides the first recommendations for post-trial responsibilities in implantable neural device research developed for a specific jurisdictional context: Australia. By embedding this consensus exercise in the Australian innovation context and linking prescriptive requirements to responsible parties, these 11 recommendations offer action-guiding direction to improve post-trial ethical practices. While their implementation will require further engagement with consumer groups, particularly with those with lived experience of the relevant conditions and prior or present use of related devices, our findings demonstrate both the feasibility and urgency of addressing post-trial responsibilities in a rapidly evolving innovation landscape. Building on existing organisational practices and expanding community involvement will be essential to ensure that participants are supported ethically and sustainably as neurotechnology advances.

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-026-01475-7.

Supplementary Material 1.

**Acknowledgements**

We would like to acknowledge Deama Amr, Tracy Cameron, Katrina Hutchison, and Jackie Leach Scully as members of the expert panel for their role in the workshops and consensus survey. We also acknowledge Georgia Ioakimidis-MacDougall and Molly Johnston for advice on survey design and operationalising our approach to measuring consensus, and Liam Robertson for assistance with organising and facilitating the workshops.

**Authors' contributions**

Nathan Higgins, John Gardner, and Adrian Carter formed part of the core team that drafted the provisional recommendations and designed and facilitated the workshops and final survey. The remaining authors were members of the expert panel that participated in the workshops and survey, and contributed substantively to the development and refinement of the recSommendations and the drafting of the manuscript. We would like to acknowledge Deama Amr, Tracy Cameron, Katrina Hutchison, and Jackie Leach Scully as members of the expert panel for their role in the workshops and consensus survey. We also acknowledge Georgia Ioakimidis-MacDougall and Molly Johnston for advice on survey design and operationalising our approach to measuring consensus, and Liam Robertson for assistance with organising and facilitating the workshops. All authors have approved the manuscript and its submission. The manuscript has not been published or submitted elsewhere. The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Funding**

This research did receive funding. Nathan Higgins is funded by an Australia Research Training Program (RTP) Stipend. Adrian Carter is funded by an Australian Research Council (ARC) Future Fellowship (ID: FT220100509). John Noel Viana is the recipient of an ARC Discovery Early Career Researcher Award (project number DE240100386) funded by the Australian Government. Allan McCay is president the Centre for Neurotechnology and Law, an organisation that has received funding from a brain-computer interface company in sponsorship of an event.

**Data availability**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

**Ethics approval and consent to participate**

This study was approved by the Monash University Human Research Ethics Committee (ID: 31526). This research was conducted in accordance with the Declaration of Helsinki and received approval from the appropriate institutional ethics committee. Documentation supporting this approval (or exemption, where applicable) is available to the Editor upon request. Informed consent was obtained from all participants. Consent covered all personally identifiable data. Consent to publication: All participant data has been deidentified, and all participants consented to the publication of their deidentified data. Clinical trial number: not applicable.

**Competing interests**

Allan McCay is president the Centre for Neurotechnology and Law, an organisation that has received funding from a brain-computer interface company in sponsorship of an event.

**Author details**

[1]School of Psychological Sciences, Monash University, Melbourne, Australia
[2]Monash Bioethics Centre, School of Philosophical, Historical, and Indigenous Studies, Monash University, Melbourne, Australia
[3]Faculty of Medicine, Centre for Health Informatics (CHI), Health and Human Sciences, Australian Institute of Health Innovation, Macquarie University, Sydney, Australia
[4]Special Counsel Wotton Kearney Solicitors, Member Australian Human Rights Commission Advisory Group on Neurotechnology, Melbourne, Australia
[5]EthicsLab, School of Humanities, University of Tasmania, Hobart, Australia
[6]Medtechnique Consulting, Sydney, Australia

[7]Department of Biomedical Engineering, University of Melbourne, Melbourne, Australia
[8]The Bionics Institute, Fitzroy, Melbourne, Australia
[9]Department of Medical Bionics, University of Melbourne, Parkville, Melbourne, Australia
[10]Faculty of Law, Monash University, Melbourne, Australia
[11]Centre for Medical Ethics and Law, Faculties of Law and Medicine, The University of Hong Kong, Hong Kong, Hong Kong SAR
[12]PHG Foundation, University of Cambridge, Cambridge, UK
[13]School of Law and Humans Technology Law Centre, Queensland University of Technology, Brisbane, Australia
[14]Lived Experience Australia, Adelaide, Australia
[15]University of Sydney Law School, Sydney, Australia
[16]Research Governance & Integrity, Murdoch Children's Research Institute, Melbourne, Australia
[17]Medical School, University of Queensland, Brisbane, Australia
[18]Department of Neurosurgery, Alfred Hospital, Melbourne, Australia
[19]Deparment of Surgery, Monash University, Melbourne, Australia
[20]Justice and Technoscience Laboratory, School of Regulation and Global Governance, The Australian National University, Canberra, Australia
[21]School of Social Sciences, Monash University, Melbourne, Australia

Received: 23 December 2025 / Accepted: 30 April 2026
Published online: 12 May 2026

## References

1. Steinmetz JD, Seeher KM, Schiess N, Nichols E, Cao B, Servili C, et al. Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet Neurol. 2024;23(4):344–81. https://doi.org/10.1016/S1474-4422(24)00038-3.
2. Amadio J, Bi GQ, Boshears PF, Carter A, Devor A, Doya K, et al. Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives. Neuron. 2018;100(1):19–36. https://doi.org/10.1016/j.neuron.2018.09.021.
3. Figee M, Mayberg H. The future of personalized brain stimulation. Nat Med. 2021;27(2):2. https://doi.org/10.1038/s41591-021-01243-7.
4. Johnson KA, Dosenbach NUF, Gordon EM, Welle CG, Wilkins KB, Bronte-Stewart HM et al. Proceedings of the 11th Annual Deep Brain Stimulation Think Tank: pushing the forefront of neuromodulation with functional network mapping, biomarkers for adaptive DBS, bioethical dilemmas, AI-guided neuromodulation, and translational advancements. Front Hum Neurosci. 2024;18:1320806. https://doi.org/10.3389/fnhum.2024.1320806.
5. Rosenfeld JV. Neurosurgery and the Brain-Computer Interface. In: Di Ieva A, Suero Molina E, Liu S, Russo C, editors. Computational Neurosurgery. Cham: Springer Nature Switzerland; 2024. pp. 513–27. Available from: https://doi.org/10.1007/978-3-031-64892-2_32. [Cited 23 Nov 2025].
6. Card NS, Wairagkar M, Iacobacci C, Hou X, Singer-Clark T, Willett FR, et al. An Accurate and Rapidly Calibrating Speech Neuroprosthesis. N Engl J Med. 2024;391(7):609–18. https://doi.org/10.1056/NEJMoa2314132.
7. Oxley TJ, Yoo PE, Rind GS, Ronayne SM, Lee CMS, Bird C, et al. Motor neuroprosthesis implanted with neurointerventional surgery improves capacity for activities of daily living tasks in severe paralysis: first in-human experience. J NeuroIntervent Surg. 2021;13(2):102–8. https://doi.org/10.1136/neurintsurg-2020-016862.
8. Patrick-Krueger KM, Burkhart I, Contreras-Vidal JL. The state of clinical trials of implantable brain–computer interfaces. Nat Rev Bioeng. 2024 Sep;20. https://doi.org/10.1038/s44222-024-00239-5.
9. Willett FR, Kunz EM, Fan C, Avansino DT, Wilson GH, Choi EY, et al. A high-performance speech neuroprosthesis. Nature. 2023;620(7976):7976. https://doi.org/10.1038/s41586-023-06377-x.
10. Ienca M, Valle G, Raspopovic S. Clinical trials for implantable neural prostheses: understanding the ethical and technical requirements. Lancet Digit Health. 2025;7(3):e216–24. https://doi.org/10.1016/S2589-7500(. 24)00222-X PubMed PMID: 39794174.
11. Soldado-Magraner J, Antonietti A, French J, Higgins N, Young MJ, Larrivee D, et al. Applying the IEEE BRAIN neuroethics framework to intra-cortical brain-computer interfaces. J Neural Eng. 2024;21(2):022001. https://doi.org/10.1088/1741-2552/ad3852.
12. Vansteensel MJ, Klein E, van Thiel G, Gaytant M, Simmons Z, Wolpaw JR, et al. Towards clinical application of implantable brain–computer interfaces for people with late-stage ALS: medical and ethical considerations. J Neurol. 2023;270(3):1323–36. https://doi.org/10.1007/s00415-022-11464-6.
13. Hendriks S, Grady C, Ramos KM, Chiong W, Fins JJ, Ford P, et al. Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research With Neural Devices: A Review. JAMA Neurol. 2019;76(12):1506. https://doi.org/10.1001/jamaneurol.2019.3523.
14. Hendriks S, Hsu N, Beckel-Mitchener AC, Ngai J, Grady C. Continuing trial responsibilities for implantable neural devices. Neuron. 2023;S089662732300541X. https://doi.org/10.1016/j.neuron.2023.07.008.
15. World Medical Association. WMA Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Participants. 2024.
16. Fins JJ, Merner AR, Wright MS, Lázaro-Muñoz G. Identity Theft, Deep Brain Stimulation, and the Primacy of Post-trial Obligations. Hastings Cent Rep. 2024;54(1):34–41. https://doi.org/10.1002/hast.1567.
17. Goering S, Brown AI, Klein E. Brain Pioneers and Moral Entanglement: An Argument for Post-trial Responsibilities in Neural-Device Trials. Hastings Cent Rep. 2024;54(1):24–33. https://doi.org/10.1002/hast.1566.
18. Harris A, Gilbert F. Need for greater post-trial support for clinical trial participants assessing high-risk, irreversible treatments. J Med Ethics. 2024. https://doi.org/10.1136/jme-2023-109719. jme-2023-109719.
19. Lázaro-Muñoz G, Yoshor D, Beauchamp MS, Goodman WK, McGuire AL. Continued access to investigational brain implants. Nat Rev Neurosci. 2018;19(6):317–8. https://doi.org/10.1038/s41583-018-0004-5.
20. Sierra-Mercado D, Zuk P, Beauchamp MS, Sheth SA, Yoshor D, Goodman WK, et al. Device Removal Following Brain Implant Research. Neuron. 2019;103(5):759–61. https://doi.org/10.1016/j.neuron.2019.08.024.
21. Bergstein B. Paralyzed again. Technol Rev. 2015;118(3):56–60.
22. Strickland E, Harris M. Their bionic eyes are now obsolete and unsupported. IEEE Spectr. 2022;15. https://spectrum.ieee.org/inchfab.
23. Drew L. Like taking away a part of myself —— life after a neural implant trial. Nat Med. 2020;26(8):1154–6. https://doi.org/10.1038/d41591-020-00028-8.
24. Drew L. Abandoned: the human cost of neurotechnology failure. Nature. 2022. https://doi.org/10.1038/d41586-022-03810-5.
25. Underwood E. Researchers grapple with the ethics of testing brain implants. Science. 2017;31. https://doi.org/10.1126/science.aar3698.
26. Gilbert F, Ienca M, Cook M. How I became myself after merging with a computer: Does human-machine symbiosis raise human rights issues? Brain Stimul. 2023;16(3):783–9. https://doi.org/10.1016/j.brs.2023.04.016.
27. Dasgupta I, Klein E, Cabrera LY, Chiong W, Feinsinger A, Fins JJ, et al. What Happens After a Neural Implant Study? Neuroethics Expert Workshop on Post-Trial Obligations. Neuroethics. 2024;17(2):22. https://doi.org/10.1007/s12152-024-09549-2.
28. Higgins N, Gardner J, Wexler A, Kellmeyer P, O'Brien K, Carter A. Post-trial access to implantable neural devices: an exploratory international survey. BMJ Surg Interv Health Technol. 2024;6(1):e000262. https://doi.org/10.1136/bmjsit-2024-000262.
29. Schönweitz FB, Ruess AK, McLennan S, Buyx A, Ienca M. Where is the exit? The ethical importance of exit plans in clinical trials with neural implants. Brain Stimul. 2024;17(5):1145–54. https://doi.org/10.1016/j.brs.2024.09.010.
30. Aldinger C, Bierer B, Li R, Van Campen L, Barnes M, Bedell E et al. December. MRCT Center Post-Trial Responsibilities Framework Continued Access to Investigational Medicines. Guidance Document. Version 1.0, 2016. 2016.
31. Okun MS, Marjenin T, Ekanayake J, Gilbert F, Doherty SP, Pilkington J, et al. Definition of Implanted Neurological Device Abandonment: A Systematic Review and Consensus Statement. JAMA Netw Open. 2024;7(4):e248654. https://doi.org/10.1001/jamanetworkopen.2024.8654.
32. van Stuijvenberg OC, Bassil KC, de Vos CC, Geleijnse G, Noordmans HJ, Broekman MLD et al. Ethical Guidance for Investigational Implantable Neural Device Studies: Recommendations for Researchers and Research Ethics Committees. Neuromodulation: Technology at the Neural Interface. 2026. https://doi.org/10.1016/j.neurom.2025.12.011.
33. Montgomery R, Mankekar G, Montgomery R, Mankekar G. From Silence to Sound: Graeme Clark's Cochlear Implant. Cureus. 2024;16. https://doi.org/10.7759/cureus.68580.
34. Halliday AJ, Gillinder L, Lai A, Seneviratne U, Fontenot H, Cameron T, et al. The UMPIRE study: A first-in-human multicenter trial of bilateral subscalp monitoring for epileptic seizure detection. Epilepsia. 2025;66(9):3426–39. https://doi.org/10.1111/epi.18458.

35. Mitchell P, Lee SCM, Yoo PE, Morokoff A, Sharma RP, Williams DL, et al. Assessment of Safety of a Fully Implanted Endovascular Brain-Computer Interface for Severe Paralysis in 4 Patients: The Stentrode With Thought-Controlled Digital Switch (SWITCH) Study. JAMA Neurol. 2023 Jan;9. https://doi.org/10.1001/jamaneurol.2022.4847.
36. Carter A, Richards LJ, Apthorp D, Azghadi MR, Badcock DR, Balleine B, et al. A Neuroethics Framework for the Australian Brain Initiative. Neuron. 2019;101(3):365–9. https://doi.org/10.1016/j.neuron.2019.01.004.
37. Prior DR, Brennan T. R&D and innovation in Australia: 2024 update. 2024.
38. Jorm AF. Using the Delphi expert consensus method in mental health research. Aust N Z J Psychiatry. 2015;49(10):887–97. https://doi.org/10.1177/0004867415600891.
39. Niederberger M, Spranger J. Delphi Technique in Health Sciences: A Map. Front Public Health. 2020;8:457. https://doi.org/10.3389/fpubh.2020.00457.
40. Bautista C, Hinkle JL, Alexander S, Hundt B, Rhudy L. A Delphi Study to Establish Research Priorities for Neuroscience Nursing. J Neurosci Nurs. 2022;54(2):74–9. https://doi.org/10.1097/JNN.0000000000000637.
41. Fitch K, editor. The Rand/UCLA appropriateness method user's manual. Santa Monica: Rand; 2001. 109 p. (MR / Rand DG-XII/RE; no. 1269).
42. Forsman AK, Wahlbeck K, Aaro LE, Alonso J, Barry MM, Brunn M, et al. Research priorities for public mental health in Europe: recommendations of the ROAMER project. Eur J Public Health. 2015;25(2):249–54. https://doi.org/10.1093/eurpub/cku232.
43. Ives J, Dunn M, Molewijk B, Schildmann J, Bærøe K, Frith L, et al. Standards of practice in empirical bioethics research: towards a consensus. BMC Med Ethics. 2018;19(1):68. https://doi.org/10.1186/s12910-018-0304-3.
44. Gattrell WT, Logullo P, van Zuuren EJ, Price A, Hughes EL, Blazey P, et al. ACCORD (ACcurate COnsensus Reporting Document): A reporting guideline for consensus methods in biomedicine developed via a modified Delphi. PLoS Med. 2024;21(1):e1004326. https://doi.org/10.1371/journal.pmed.1004326.
45. Drolet MJ, Rose-Derouin E, Leblanc JC, Ruest M, Williams-Jones B. Ethical Issues in Research: Perceptions of Researchers, Research Ethics Board Members and Research Ethics Experts. J Acad Ethics. 2023;21(2):269–92. https://doi.org/10.1007/s10805-022-09455-3.
46. Hansson SO. How to Perform an Ethical Risk Analysis (eRA). Risk Anal. 2018;38(9):1820–9. https://doi.org/10.1111/risa.12978.
47. Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM, et al. Defining consensus: A systematic review recommends methodologic criteria for reporting of Delphi studies. J Clin Epidemiol. 2014;67(4):401–9. https://doi.org/10.1016/j.jclinepi.2013.12.002.
48. Bernstein M. Fully informed consent is impossible in surgical clinical trials. Can J Surg. 2005;48(4):271–2. PubMed PMID: 16149359; PubMed Central PMCID: PMC3211530.
49. Stevens I, Gilbert F. Ethical examination of deep brain stimulation's 'last resort' status. J Med Ethics. 2021;47(12):e68–68. https://doi.org/10.1136/medethics-2020-106609.
50. Sankary LR, Zelinsky M, Machado A, Rush T, White A, Ford PJ. Exit from Brain Device Research: A Modified Grounded Theory Study of Researcher Obligations and Participant Experiences. AJOB Neurosci. 2021;1–12. https://doi.org/10.1080/21507740.2021.1938293.
51. Boulicault M, Goering S, Klein E, Dougherty D, Widge AS. The Role of Family Members in Psychiatric Deep Brain Stimulation Trials: More Than Psychosocial Support. Neuroethics. 2023;16(2):14. https://doi.org/10.1007/s12152-023-09520-7.
52. Thomson CJ, Segrave RA, Racine E, Warren N, Thyagarajan D, Carter A. He's Back so I'm Not Alone: The Impact of Deep Brain Stimulation on Personality, Self, and Relationships in Parkinson's Disease. Qual Health Res. 2020;30(14):2217–33. https://doi.org/10.1177/1049732320951144.
53. Thomson CJ, Segrave RA, Fitzgerald PB, Richardson KE, Racine E, Carter A. Nothing to Lose, Absolutely Everything to Gain: Patient and Caregiver Expectations and Subjective Outcomes of Deep Brain Stimulation for Treatment-Resistant Depression. Front Hum Neurosci. 2021;15:565. https://doi.org/10.3389/fnhum.2021.755276.
54. National Health and Medical Research Council. Human Research Ethics Application form. 2025. Available from: https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-application-form. Accessed 1 Aug 2025.
55. Therapeutic Goods Administration. Australian clinical trial handbook. 2025. Available from: https://www.tga.gov.au/resources/guidance/australian-clinical-trial-handbook. Accessed 23 Apr 2025.
56. National Health and Medical Research Council. Safety monitoring and reporting in clinical trials involving therapeutic goods. 2016. Available from: https://www.nhmrc.gov.au/sites/default/files/2023-03/NHMRC-guidance-safety-monitoring-and-reporting.pdf.Accessed 24 Apr 2025.
57. Brown AI, MacDuffie KE, Goering S, Klein E. The Wheels That Keep Me Goin': Invisible Forms of Support for Brain Pioneers. Neuroethics. 2025;18(1):21. https://doi.org/10.1007/s12152-025-09593-6.
58. Levy L, Ebadi H, Peabody Smith A, Taiclet L, Pouratian N, Feinsinger A. Disentangling Function from Benefit: Participant Perspectives from an Early Feasibility Trial for a Novel Visual Cortical Prosthesis. AJOB Neurosci. 2023;1–19. https://doi.org/10.1080/21507740.2023.2257152.
59. Gilbert F, Tubig P, Harris AR. Not-So-Straightforward Decisions to Keep or Explant a Device: When Does Neural Device Removal Become Patient Coercion? AJOB Neurosci. 2022;13(4):230–2. https://doi.org/10.1080/21507740.2022.2126544.
60. Stein A, Higgins N, Gajwani M, Gericke CA. The treatment gap for deep brain stimulation in Parkinson's disease: a comparative analysis of cost and utilisation in high-income countries. Aust Health Rev. 2024;48(5):497–505. https://doi.org/10.1071/AH24036.
61. Medical Technology Association of Australia. Clinical Investigation Research Agreements. 2025. Available from: https://www.mtaa.org.au/clinical-investigation-research-agreements.Accessed 29 Apr 2025.
62. Medicines Australia. Clinical Trial Research Agreements – Medicines Australia. 2025. Available from: https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/.Accessed 28 Apr 2025.
63. Therapeutic Goods Administration. An Action Plan for Medical Devices – Improving Australia's medical device regulatory framework. Australian Government Department of Health, Disability and Ageing; 2019. Available from: https://www.health.gov.au/resources/publications/an-action-plan-for-medical-devices-improving-australias-medical-device-regulatory-framework?language=en. [Cited 24 Nov 2025].
64. Ausbiotech M, Australia, Medical Technology Association of Australia. Research and Development Taskforce submission in response to the Consultation on proposed regulatory changes for clinical trials of medical devices. 2022. Available from: https://www.ausbiotech.org/documents/item/720
65. Fins JJ. Deep Brain Stimulation, Free Markets and the Scientific Commons: Is It time to Revisit the Bayh-Dole Act of 1980? Neuromodulation: Technol Neural Interface. 2010;13(3):153–9. https://doi.org/10.1111/j.1525-1403.2009.00238.x.
66. Food and Drug Administration. Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health. FDA. 2024. Available from: https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health. [Cited 24 Nov 2025].
67. Organisation for Economic Co-operation and Development. OECD. P. 2017. New Health Technologies: Managing Access, Value and Sustainability. Available from: https://www.oecd.org/en/publications/managing-new-technologies-in-health-care_9789264266438-en.html. https://doi.org/10.1787/9789264266438-en. [Cited 24 Nov 2025].
68. Therapeutic Goods Administration. UDI requirements | Therapeutic Goods Administration (TGA). Therapeutic Goods Administration (TGA); 2025. Available from: https://www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique-device-identification-udi-hub/udi-information-sponsors-and-manufacturers/udi-requirements. [Cited 24 Nov 2025].
69. Therapeutic Goods Administration. Understanding your post-market responsibilities for medical devices | Therapeutic Goods Administration (TGA). Therapeutic Goods Administration (TGA); 2022. Available from: https://www.tga.gov.au/resources/guidance/understanding-your-post-market-responsibilities-medical-devices. [Cited 24 Nov 2025].
70. Southwood N. Does Ought Imply Feasible? Philos Public Affairs. 2016;44(1):7–45. https://doi.org/10.1111/papa.12067.


## Publisher's note