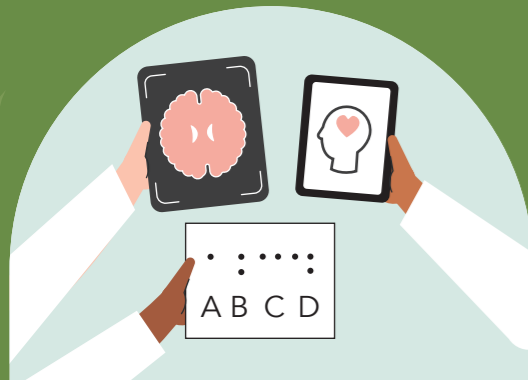


# How can we ensure that research into investigational neural implants thrives?

## Recommendations for review questions that align with the challenges of brain implant research

Research into investigational neural implants presents unique challenges. These include the lack of alternative treatments, implant-related decisions, impact on the self of self and physical, psychological, financial, and data-related risks. The questions below aim to help you safeguard the scientific and ethical quality of the study and assess whether study participants are adequately protected. They are based on ethical and legal frameworks as well as scientific literature.

- *ethical guidelines*
- *legislation and legal regulations*
- *scientific literature*



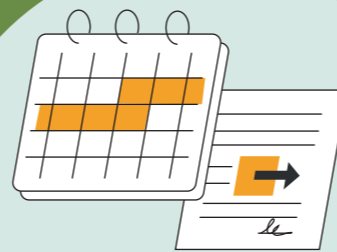
### Composition of the study team

- Is there sufficient time and resources dedicated to tailor communication to the participant, such as sign language and braille?
- Is the study team multidisciplinary, combining medical, psychological, and technical expertise to support participants?
- Have arrangements been made to preserve continuity of (after)care and support in case of team transitions?



### Recruitment and selection of participants

- What is the justification for exclusion criteria? Does harm due to exclusion weight out harm due to inclusion?
- How is assessed whether individuals can handle the burden of the study in the selection of participants?
- How is the emotional resilience of study participants taken into account during selection to prevent disappointment and psychological harm?
- How is determined whether study participants have sufficient support from a caregiver, and is additional help provided if a caregiver is not available?



### Information and consent

- How is the information made understandable, repeated over time, and tailored to the changing needs of participants?
- How are the expectations of potential participants regarding the goals, burden, and outcomes of the study managed and aligned to prevent misunderstandings and therapeutic misconceptions?
- Are participants informed in advance and repeatedly about post-trial arrangements, such as explantation, aftercare, and possible consequences?
- What are the implications of withdrawing from the study (with regard to explantation)?
- How is the voluntariness of consent ensured, considering the possible relationship with the study team and the decision-making capacity of the participant?



### Benefits and risks

- Do study endpoints align with what participants consider valuable?
- What is known about the quality and stability of the material, device, and software, especially in long-term implantation?
- What is known about the risks of both long-term implantation and explantation, including physical and psychological aspects?
- Have risks related to exclusion from future implant studies or treatments been considered, for example due to scar tissue formation or outdated hardware?
- Are there risks for future diagnostic or treatment procedures (eg MRI), and is this communicated to the participant?
- Is the psychological well-being of participants actively monitored and supported during and after the study?
- Have measures been taken to prevent privacy risks for both participants and bystanders?



### Post-trial arrangements

- Are post-trial arrangements, such as aftercare or continued access, in place for all participants, regardless of their individual outcome?
- How is ensured that post-trial arrangements align with the individual needs of participants and caregivers?
- Is post-trial access in place for participants who have experienced benefits?
- Do participants have a choice regarding explantation during and after the study?
- How are financial risks, such as manufacturer bankruptcy, managed with appropriate aftercare?
- Have agreements been made to collect long-term data on safety and effectiveness after the study concludes?
- Which protective measures against unwanted media attention, tailored to the preferences of participants, have been implemented?
- Have the financial risks of participation, such as costs for explantation or aftercare, been identified and minimized?
- How are the rights of participants protected in the event of the manufacturer's bankruptcy?