Informed Consent for Early Feasibility Device Studies: Experiences with Implanted Brain-Computer Interface Trials

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Early Feasibility Study

- Limited clinical investigation of a device that is early in development
- Typically limited to a small number of participants
- Used to evaluate initial clinical safety and device functionality
- Conducted under an FDA Investigational Device Exemption

Sensorimotor BCI

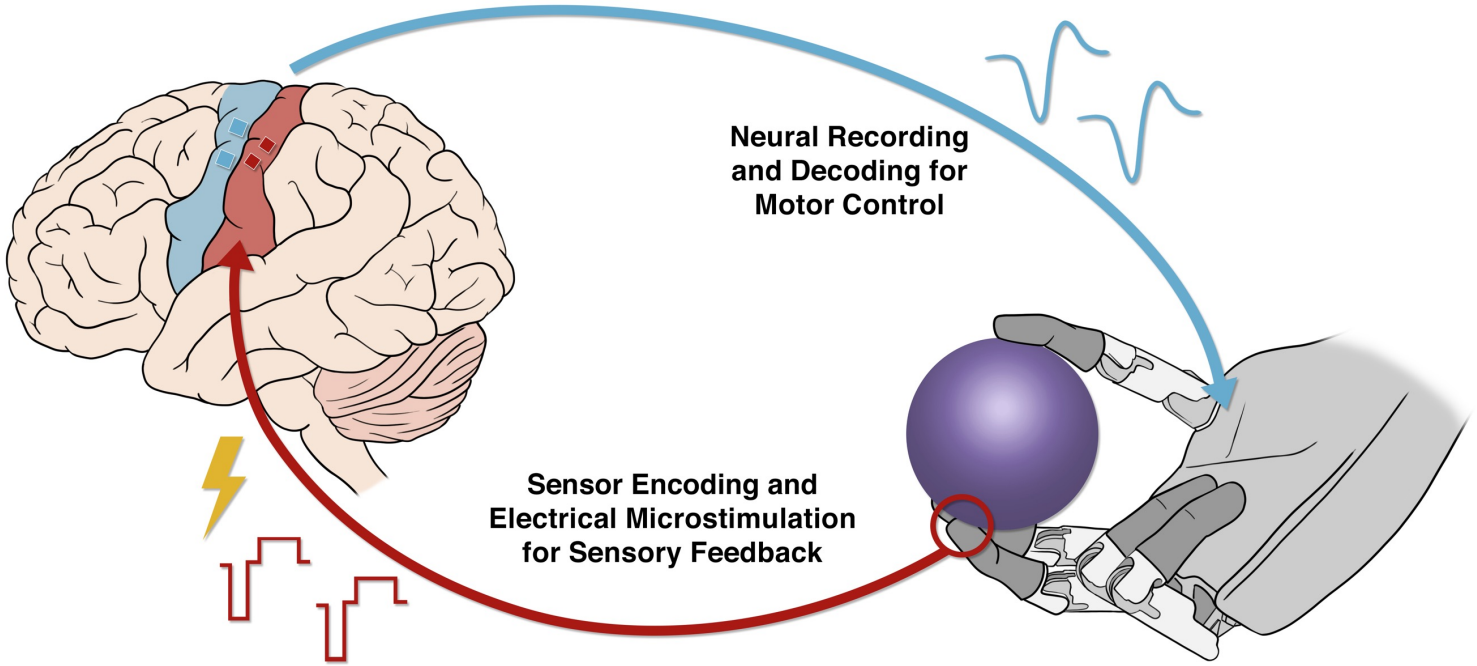
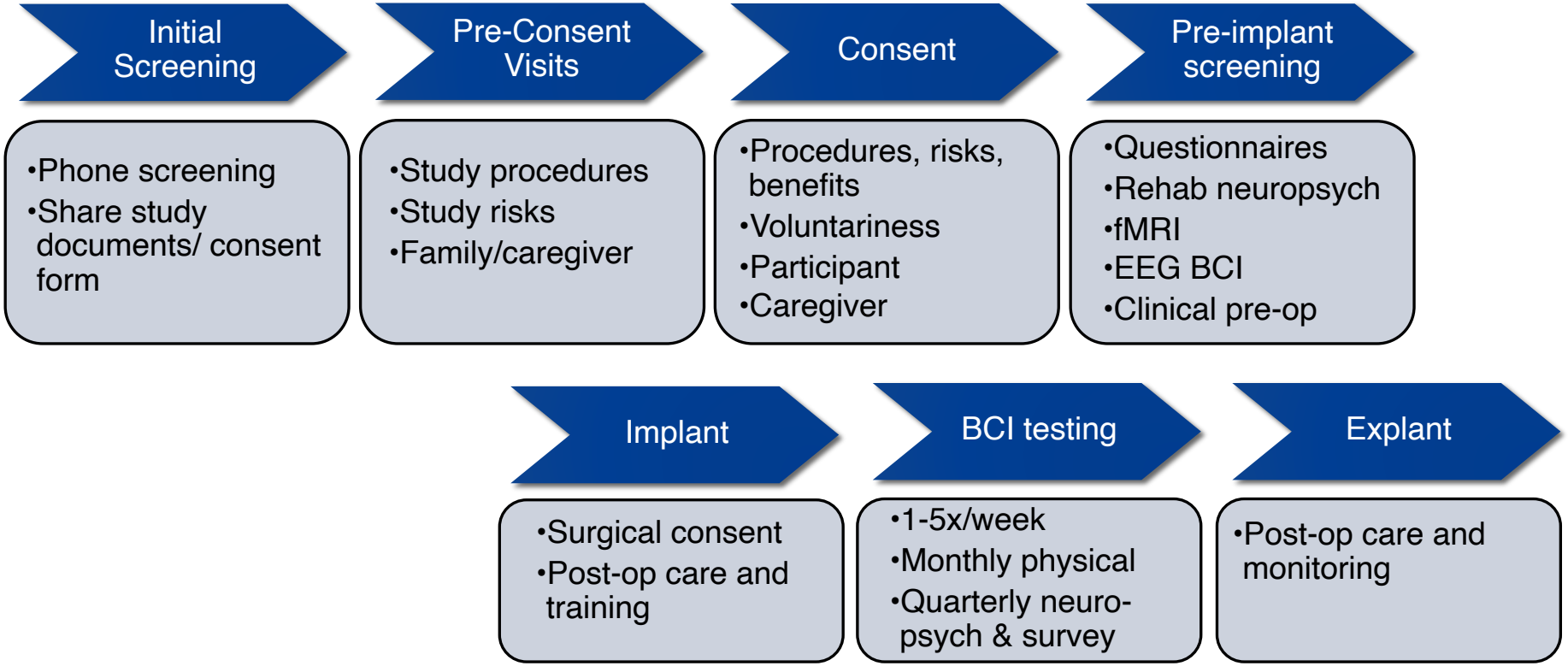


Image Credit: Kenzie Green

Pitt/U Chicago Study Overview

- **Goal:** First-in-human study to demonstrate the long term safety and efficacy of a sensorimotor BCI
- **Target population:** Adults with chronic upper limb impairments who are unable to perform functional activities with their hand
- **Risk/benefit:** Significant risk study. No direct benefit to participants. They will contribute to development of devices that will benefit people with tetraplegia in the future.
- **Study design:** Study participants complete ~3 days of testing per week for 1-10 years after implant

Study design



Opportunities to improve informed consent

- Provide information, including text/photos/videos, prior to the formal consent visit
- Informed consent documents may be 20-30 pages long
  - Can identify key points that are discussed individually and documented
  - Can include family/care partners in these discussions
- Incorporate pre-implant study visits to improve understanding of logistics/study procedures
- Ongoing monitoring and consent