POSITION PAPER
(jointly prepared by ISPO and Exceed dated 24 March 2021)

Ethical Considerations and Approaches for Conducting Clinical Research Studies related to Prosthetics, Orthotics and Wheelchair Technology in the Low- and Middle-Income Countries

Introduction

Rapid developments in prosthetics, orthotics and wheelchair technology have increased clinical research and development initiatives worldwide. Testing technology involving human subjects / participants creates ethical concerns that are under-explored and become a critical issue for prosthetists, orthotists, researchers and their clients, especially those in the low- and middle-income countries.

While some research initiatives have aligned with existing institutions, companies, and service providers; some research emerging from institutions / organisations with non-clinical and non-assistive technology backgrounds have raised considerable foundation for concerns. It is essential to develop, apply and promote appropriate and clear guiding principles for institutions / organisations conducting clinical research studies or trials, particularly in the low- and middle-income countries. Thus, practicing professionals can enable people with disabilities (often among the most excluded and vulnerable group in the society) to provide informed consent, make informed choices, and facilitate their active engagement in clinical research studies or trials without physical, psychological, and socioeconomic harm.

The outcome of the consultation between ISPO and Exceed Research Network (ERN) has led to the development of the guiding principles, laid out below, specifically directed towards the clinical research studies or technology trials involving people with disability (not on broader research into disability-related issues).

The 1978 “Belmont Report" established the foundation for protecting all persons participating in research studies and identified three core principles that should be applied when involving human subjects / participants for research purposes:

1. **Respect for persons**
   Protecting the autonomy of all people and treating them with courtesy and respect, and allowing for informed consent. Researchers must be truthful and conduct no deception.
2. **Beneficence**
   The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research participants.
3. **Justice**
   Ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly (the fair distribution of costs and benefits to potential research participants) and equally.

These three core principles provided a reference point for an initial discussion among a core group of international organisations, comments and feedback were aggregated, and some important principles were generated in the following table.

Ethical Considerations and Approaches
(from investigators to subjects / participants, and from research planning to outcome measures)

1	**Approval from Institutional Review Board (IRB)** Any trials of prosthetic, orthotic, and mobility devices that involve the device being worn by a human subject / participant must, at the outset, gain approval from an IRB at both the clinical trial site and the institution / organisation of the Principal Investigator (PI). In addition, device testing should prioritize the benefit to the subjects / participants over the needs of the researchers; should not harm the subjects / participants physically, psychologically, socially, or economically; should not deprive the subjects / participants from routine prosthetic / orthotic / wheelchair service and options for future care (e.g., making them ineligible for other standard therapies) nor should it hinder subject / participant participation in the diversity of their community.
2	**Safety Standards and Measures** Where engineering safety standards exist, prosthetic, orthotic, and mobility devices should meet those minimum strength and durability standards. As part of a risk assessment, researchers should make all possible efforts to only test devices where the risk of catastrophic failure, adverse reaction, or injury to the subjects / participants is minimal. Subjects / participants and supervising local professionals should have the authority to withdraw from the trial if they perceive any unacceptable risk.
3	**First Trial in the Source Country** Devices or techniques, especially those developed outside the country where human testing is taking place, should not have their first human trial in the participating centre because expert human resources, advanced materials, or technical fixes are potentially unavailable / hard to access. The outcomes of the trials and testing (if possible, peer reviewed) in the source country should be available and accessible for the staff of the participating trial centre before the trial starts, in the low- and middle-income country.
4	**Qualified and Experienced Researchers** Human testing of prosthetic, orthotic, and mobility devices should be carried out in collaboration with qualified and experienced Prosthetists, Orthotists, or trained wheelchair practitioners who have strong links to the country / culture and who have had training and exposure to good clinical practices in research processes and methodologies. These professionals should be based in the participating trial centre and be available to advise subjects / participants for the whole period of the trial and not only on sporadic visits. The PI is responsible to ensure qualified staff members are engaged and have technical skills to carry out the work of the trial, safely and effectively.
5	**Support to the Participating Centres** The participating centres in the low- and middle- income countries should not be expected to bear the costs of materials, personnel, and administration of the clinical trials, but should have all trial costs covered by the researchers, so as not to deplete resources aimed at clinical services. Procedures should be put in place to avoid bias related to project funding. To ensure independence, funding organisations should not have the ability to control the trial design and delivery.
6	**Preparation of the Onsite Research Partners** Research partners should be fully trained in techniques of fitting and maintaining the trial technology and in the delivery of the research project, including how to report and escalate adverse events, fault identification, and feel confident removing a subject / participant from the trial if requested or clinically indicated. Where possible, the participating research partners should

	have access to a clinic team or have a sound referral system, should additional services be needed. Researchers should consider the subjects / participants and their co-morbidities, that might increase risk of injury or harm during the trial. Co-morbidities should be judged as part of the risk assessment, and adequate resources should be put in place to monitor and assist accordingly.
7	**The Subjects' / Participants' Understanding, Agreement, and Rights** The subjects / participants in the clinical trials should have sufficient time, adequate language and literacy, and mentored support to consider the implications of taking part in the research trials, and should be able to demonstrate understanding that their participation in the trial is voluntary and their ongoing clinical services at the rehabilitation clinic are not connected and will not be effected if they decline.
8	**Reimbursements to the Subjects / Participants** Consideration should be taken that costs should be covered, when considering the involvement of the subjects / participants who are unable to access / travel to the participating trial centre without financial burden, so as to minimise the impact of adverse / unforeseen trial related events on their quality of life and socioeconomic situation. In addition, subjects / participants in the trial could be reimbursed for expenses and loss of earnings at a rate that does not constitute unethical coercion, nor does it create economic disadvantage.
9	**Trial Exit Arrangement** The onsite research partners should be clear, in the social and cultural context, that the subjects / participants have demonstrated informed and risk aware consent (in writing) and shown their willingness to take part in the trial. The subjects / participants should also demonstrate awareness of how they can exit from the trial and where and how they can seek assistance in the event of an adverse reaction or if they have a complaint. Researchers should be fully aware that the subjects / participants are not coerced into participation, or into presenting a positive outcome. Subjects / participants should demonstrate awareness that their trial devices will be returned to the researcher at the end of the trial. In cases where the subject / participant already has an appropriate device, an exit strategy should be in place to return the subject / participant to his/her previous technology after the trial. If the subject / participant possesses an inferior device, or has no device before the trial, the researcher should consider carefully the ethic and practical considerations of either removing the trial device, or leaving it with the subject / participant perhaps with no technical support. The decision should be documented and agreed with the subject / participant and the local institution.

Prospective researchers are encouraged to investigate the local / regional context to determine if relevant ethical research practices / training already exists (e.g. government, universities or organizations). Given the appropriate environment, these opportunities may provide better assurance that ethical research practices are being followed and are in place.

The suggested ethical considerations and approaches aim to provide useful guidelines for all the related parties to conduct clinical research studies related to prosthetics, orthotics, and wheelchair technology, especially those in the low- and middle-income countries. This document will be reviewed regularly to cope with this ever-changing world.

End