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How can we improve the informed consent process for first-in-human stem cell trials in Parkinson's disease?

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Neurorestorative approaches in Parkinson's disease (PD) based upon new stem cell technologies are imminent. As clinical trials are starting, it is critical to consider how to best ensure a genuinely informed consent. We therefore focused upon current barriers to such a goal and identified the following themes: (1) Barriers to adequate disclosure of risks and benefits (investigator-dependent): In first-in-human trials, risks and benefits are incompletely defined. A substantial literature in fetal tissue transplant in PD is only partially applicable, and the possibility of serious risks remains, including tumor formation, graft rejection, and risks of immunosuppressive agents if administered. (2) Barriers to understanding clinical research methodology (participant-dependent): Research participants may have difficulties understanding concepts integral to clinical research, such as equipoise. There is also strong evidence that the therapeutic misconception influenced participant's consent in previous surgical trials in PD. Cognitive dysfunction, common in PD, may or may not impair understanding of informed consent information, thus complicating evaluation of capacity to consent. (3) Need for extended consent process (investigator and participant-dependent): The traditional model of a single limited visit to address informed consent appears to be insufficient in upcoming clinical trials that involve complex scientific underpinnings, uncertainty in risks and benefits, and recruitment of participants with a neurodegenerative disorder that commonly affects cognition. Extended informed consent processes to consider include the use of multimedia educational materials, assignation of a "research partner", and multiple disclosure sessions.

Biography

Claire Henchcliffe has received her Doctorate at Oxford University UK. After completing Medical Training at the College of Physicians and Surgeons of Columbia University, New York and the New York Presbyterian Hospital, she established the Weill Cornell Parkinson's Disease and Movement Disorders Institute, New York, where she serves as a Director. She is a Vice Chair for Clinical Research and Associate Professor of Neurology at the Weill Cornell Medical College, New York and combines clinical practice and research in Parkinson's disease. Her research interests focus on developing new therapies for Parkinson's disease, in particular cell-based approaches and optimizing clinical trial designs.

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