

# The Sham Arm in Neurological Clinical Trials: Questions & Reflections from the Parkinson's Community

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# PDF's Role as a Link Between Clinical Research and People with Parkinson's

- Identifying and Addressing Barriers to Clinical Trial Participation
- Leadership of *PDtrials* and the website *PDtrials.org*
- Clinical Research Learning Institute



# Sham Surgery: A Demanding Test Case

- Invasiveness of the procedure
- Questions as to whether there may be less invasive alternatives to sham surgery
- The record of failed trials involving surgical procedures



# Informal Surveys of People with Parkinson's Attitudes on the Sham Surgery Issue

- More than half had participated in clinical trials
- Most believed that the scientific information to be gained from sham-surgery controlled trials was not worth the risk to trial participants
- Most would not participate in a trial even if sham surgery was minimally invasive

• Almost all would not participate in a trial if the sham surgery procedure penetrated



# Most Common Survey Responses

- “There must be another way [other than sham surgery]”
- “Only the most desperate patients would agree to sham surgery”
- “We do not know enough about the placebo effect to justify the use of sham surgery”
- “Sham surgery is unethical”

(source: Parkinson’s Pipeline Project Survey, June 2010)



# Commonly Asked Questions from the Parkinson's Community about Sham Surgery as the "Gold-Standard" Control in Surgical Trials



# Are There Alternatives to Sham Surgery in Controlling for the Placebo Effect?

- Using historical controls or “best medical or surgical practice” as comparators?
- Increasing trial duration beyond the placebo period?
- Reducing wide variability among trial participants?



# Would Better Understanding of the Placebo Effect Reduce the Need for Sham Surgery?

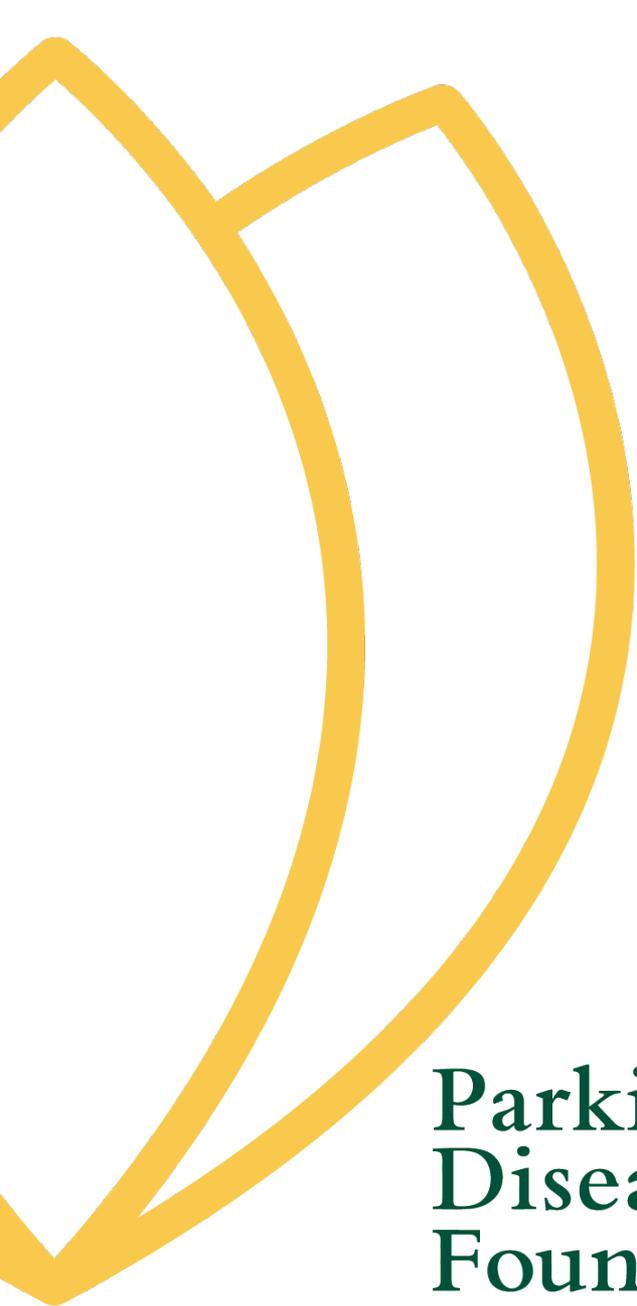
- Studies of placebo effect in Parkinson's rarely exceed six months
- A need to gather and analyze longer-term data



# Including People with Parkinson's in the Clinical Research Process

- Recognizing, respecting and building trust
- Collaborating with ALL stake-holders in the process: sponsors, investigators and regulators
- Providing specific roles: IRBs, advisors to FDA, advising in the process of trial design





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