

MEDTRONIC CLINICAL TRIALS PRINCIPLES

Medtronic is committed to the practice of evidence-based medicine. Facilitating patient access to life-saving and supportive device therapies requires world-class clinical and economic outcomes evidence. As a leader and through the Medtronic Mission, we are dedicated to scientific integrity and ethical principles in the design, conduct and reporting of human subjects research. The well-being of patient participants is of paramount concern.

We recognize the importance of external perception and support efforts to increase transparency for clinical trials that will promote continued public trust and safety.

The following principles are used to guide Medtronic clinical trials, those studies that are prospectively designed to develop safety and efficacy data that will directly impact clinical practice.

- 1) Medtronic clinical trials will be conducted to provide relevant data in order to help answer important open questions pertaining to product safety, efficacy, cost-effectiveness and appropriate utilization.
- 2) Medtronic clinical trials will be designed without bias and with the necessary scientific rigor to ensure that results are statistically meaningful and defensible.
- 3) Medtronic clinical trials will be conducted in compliance with all governing laws and regulations, and with adequate oversight to ensure that outcomes are valid and appropriately documented.
- 4) Medtronic clinical trial outcomes, whether positive or negative, will be made public* in an appropriate manner.
- 5) Medtronic clinical trial outcomes will be presented without bias and with full disclosure.
- 6) Individuals and institutions involved in designing and conducting Medtronic clinical trials and presenting clinical data from them will be compensated fairly and equitably, taking into account all circumstances surrounding the particular trial, including general market rates for similar trials as well as market compensation paid to the individuals and institutions by other parties. In this regard, Medtronic stock or stock options will not be used as compensation.
- 7) All consultation with Medtronic that is provided by an investigator will comply with the "Medtronic Business Conduct Standards" on consulting, research, and advisory arrangements that establish work product and compensation rates.
- 8) A listing of all pivotal Medtronic clinical trials will be maintained and made public*, including required registration on official public databases.

*posted on www.MedtronicTrials.com