



## **Financial Conflict of Interest (FCOI) Policy - Magnus Medical**

Magnus Medical developed the following FCOI policy in compliance with HHS regulation 42 CFR Part 50 Subpart F to ensure that the design, conduct, and reporting of research associated with the NIH-supported R01 award is free from bias resulting from an investigator's conflicting financial interest.

### **NIH Definitions**

**Investigators** include the Principal Investigator/Project Director and any other individuals, regardless of title or position who is responsible for the design, conduct, or reporting of NIH-funded research, or proposed for such funding, and which may include for example, collaborators or consultants. Includes investigators who plan to participate in or who participate in NIH-funded research.

**Financial conflicts of interest** in research involve situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research.

**Significant Financial Interest** means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (patents, copyrights, and royalties from such rights) held by an investigator or the investigator's immediate family, individually or in aggregate, when such interest involves:

- Payments in excess of \$5,000 (including salary, consulting fees, royalty or licensing payments from intellectual property, and honoraria and/or gifts) received within the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from the institution);
- An equity interest in a publicly traded company worth more than \$5,000 or more than 5 percent of the business entity as determined by reference to its publicly listed price (excluding mutual funds);
- Any equity interest if the value cannot be determined by reference to publicly listed prices (i.e., an equity interest in a privately held company, such as a start-up company);
- A position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any other position of management; or
- Intellectual property rights (patents or copyrights) or royalties from such rights whose value maybe affected by the outcome of the research, including royalties distributable under institutional policy or any royalty-sharing agreements involving the institution.

### **Review, Disclosure, and Management Process**

In compliance with federal regulations, all Magnus Medical Investigators must review the 2011 revised regulation as described in 42 CFR part 50.604(a) with the Research Manager/Director

and report any current or potential financial conflicts of interest. The Research Manager/Director must immediately report any conflicts identified to the appropriate Program Official at NIH. In cases where disclosure of significant financial interest is alone is inadequate, the Research Manager/Director will arrange for the Investigators and other appropriate team members to review the disclosure directly with the appropriate NIH Program Officials. *The NIH-supported research project will not begin /resume (i.e. no federal funding may be expended) until the identified FCOI has been resolved to the satisfaction of the NIH Program Officials.*

### **FCOI in Research Involving Human Subjects**

Additional consideration will be given to conflicts of interest when the research involves human participants. In addition to the process outlined above, any significant financial conflict identified will be disclosed to the Institutional Review Board (IRB) responsible for review and approval of the associated protocols. Research will not begin/resume until the IRB has confirmed that appropriate steps have been taken to ameliorate any potential harm or potential harm to participants due to the significant financial conflict.