PROFOUND	**JOB DESCRIPTION – Clinical Operations Manager**

Description	
Job Title	Clinical Operations Manager
Reports to Title	VP Clinical Affairs
General Accountability	Our mission is to Profoundly change the standard of care by creating a tomorrow where clinicians can confidently ablate tissue with precision; a tomorrow where patients have access to safe and effective treatment options, so they can quickly return to their daily lives. Changing the standard of care is part of our fabric. We are a group of energetic, problem-solvers focused on innovation, and looking to change the world. If you want to make a Profound impact with your career, while making a difference in other people's lives, here is your chance. The Clinical Operations Manager will provide leadership, and manage a support team in executing the clinical trials. He/she is a key member of the clinical operations team dedicated to achieving and exceeding business objectives through efficient execution, high quality and timely deliverables of all associated aspects of the trial, in compliance with investigational device regulatory requirements and Good Clinical Practice guidelines.
Duties and Responsibilities	Responsible for trial management to ensure all aspects of trials are executed as planned 1. Participate in review of site contracts and budget negotiations 2. Manage clinical site preparation activities – ensure technical changes to MRI suits are implemented in timely manner 3. Clinical site validation activities – coordinate Profound and Clinical site personnel to schedule MR validation activities 4. Establish the Trial Master File at each site including essential and non-essential documents. Ensure current copies of lab certificates, regulatory approvals, clinician's credentials, etc., are updated in a timely manner and are in compliance. 5. Establish relationship with study site personnel specifically, a study nurse to keep track of patient enrollment and treatment schedules. Ensure patient follow-ups for clinical results are received in timely manner 6. Ensure the conduct of the study is in compliance with the currently approved protocol/amendment(s), with current GCP guidelines and with applicable regulatory requirements. 7. Maintain investigational product accountability and traceability – Ensure product shipped, necessary to meet study requirements and track device usage for each enrolling patient per clinical site 8. Scheduling medical monitoring visits as planned 9. Manage the clinical trial support team 10. Manage clinical trial progress and ensure completeness of documentation and data collection in adherence with the project timelines. Verifications of clinical activities and approval of invoices according to the site budget 11. Reporting status of the trial to senior management.

	12. Perform other duties as assigned to ensure successful management and completion of clinical trial

Competencies	
Education	Bachelor's degree in a clinical, scientific or health-related discipline or equivalent experience.
Certifications	n/a
Key Attributes (experience, skills and technical knowledge)	• Minimum 5 years direct experience in planning and managing all phases of clinical trials is required. • Previous experience running medical device trials is an asset. • Must have a good working knowledge of medical terminology and physiology and an excellent knowledge of applicable U.S. and international investigational regulations and guidelines. • Excellent oral and written communication, organizational and planning skills with a proven ability to manage budgets • Detail-oriented, a self-starter and be comfortable with broad responsibilities in an entrepreneurial, fast-paced, small rapidly growing company environment. • Maintains proper communications with other departments to ensure communication and good relationships in connection with matters related to clinical trial projects • Direct experience in managing a clinical trial support team is required • Travel to sites when necessary