INVESTIGATOR-INITIATED RESEARCH GUIDELINES

Our Mission

At Bruin Biometrics (BBI), we are relentlessly committed to using technology to improve the way that health care is delivered. By developing innovative medical device systems that can cost-effectively detect and monitor select medical conditions with urgent clinical need, we are doing our part to help inform clinical decisions, simplify patient care, and improve patient outcomes.

BBI supports investigator-sponsored research conducted on BBI’s SEM Scanner.

Conditions to Conduct an Investigator Initiated Study Supported by BBI

BBI is committed to improving patient care and contributing to scientific knowledge with the support of unbiased and high quality research that is designed and administered by U.S. and international based external investigators. BBI focuses on excellence in execution and significant results by applying rigorous scientific, technical and clinical standards. Information may be gathered and disseminated in peer-review publications or scientific conferences.

BBI may provide grants to support investigator initiated researched based on scientific merit of the proposal, compliance with applicable regulations and in accordance with corporate policy. The budget must be reasonable and appropriate for the proposed work. The research must be intended to:

1. Promote advances in healthcare and science.
2. Improve patient care through high quality research.
3. Conducted in compliance with all legal, ethical and professional requirements.
4. Meet the standard guidelines for support.

BBI will also take into consideration the expertise of the proposed principal investigator including their experience in the field, demonstrated success to conduct clinical trials and the resources available for the study.
Responsibilities of Investigator / Sponsor

1. Must ensure that the study is conducted in accordance with all applicable laws, protocol and guidelines.
2. Obtains all required approvals prior to the start of the study.
3. Maintains proper staffing to complete the study within the designated time frame as defined by the predetermined schedule.
4. Monitors the study to keep in accordance with predetermined design of the study.
5. Reports any safety data to regulatory authorities.
6. Inform BBI of all data and any adverse events.
7. Register the study and results on a public website, as appropriate (e.g., www.clinicaltrials.gov).

All proposals will be reviewed in accordance with BBI policy.

Review, Evaluation and Decisions are based on the following:

1. Scientific merit of the proposed study.
2. Investigator credentials and qualifications to conduct the proposed study.
3. Ability to comply with all legal, ethical and professional requirements.
4. Strategic alignment in order to deliver goals set forth by BBI
5. Budget availability.
6. Time frame in which the study is to take place.

BBI may make suggestions to improve the scientific merit of the proposal to support the criteria required by BBI, although the principal investigator will have final discretion and responsibility for the study including design, implementation, data analysis, and data dissemination. The study must comply with all laws and regulations that govern the industry applicable to the research study. The final terms between BBI and the investigator must be contained in a written agreement. BBI makes no guarantees that it will provide support for the proposal. The investigator will be notified of the outcome.

☐ By checking this box, I have read and understand the conditions and regulations set forth by BBI.