Sanara MedTech
Evidence Based Healing
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INVESTIGATOR INITIATED STUDY (IIS) PROPOSAL

Documentation to be included for Sanara MedTech Consideration.

This document describes the proposed research, activities and responsibilities outlined by the investigator with potential sponsorship support from Sanara MedTech. This document does not constitute a formal clinical study agreement. Please review the items listed and provide the requested information as available.

1. Study question to be answered through the proposed research.
2. Objectives; background and significance.
3. Methods (proposed study design, setting, sample, control, variables, etc.). Does the project involve patients or only laboratory and basic science.
4. Principal Investigator; proposed study population; sites/facilities enrolling or conducting the research (please include contact information/address for PI and each facility.
5. Has the facility given administrative approval for proposed clinical research project?
6. Timeline – study and participant duration – milestone events.
7. Description of the responsible parties assigned for accountability of tasks and deliverables; two-way communications; informed activity progress; and regulatory required record keeping.
8. Costs and billing schedule of the proposed product expenses, itemized financial support request, payment expectations. Itemized budget milestones of project with capped amounts. The responsible party along with email and phone contact information for budget and payments. The costs and plan for internal or external IRB approval of a clinical study as applicable. Please list other grants or funds for the support of the proposed project and research personnel.
9. Identification of responsible parties for literature review, protocol development, number to study for significance, data collection, statistical analysis, validation of results, and medical writing.
10. Planned project deliverables - completion and closure (Poster/Abstract/Manuscript).

Please Print Name and Title of individual completing project information if not principal investigator:

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Signature of Principal Investigator: _____Date: _____