Sensium Clinical Research Program

The Sensium Clinical Research Program encourages investigators, organizations and industry to pursue original clinical research demonstrating the benefits of continuous wireless monitoring and early detection of patient deterioration.

Sensium is an innovation-driven company comprising scientists, engineers, clinicians and business professionals, dedicated to improving patient care through the development of digital healthcare technologies. We passionately believe in the benefits of early detection of patient deterioration for general care patients who do not currently have the safety and security of continuous wireless vital sign monitoring. We understand the importance of evidence-based healthcare and are keen to partner with clinical researchers who share our ambitious view for healthcare in the 21st century.

Typical categories of research that may be eligible for support include

- Investigator-initiated studies
- Industry-sponsored research using Sensium as a monitoring or data-collection tool (e.g. pharmaceutical research)
- Studies sponsored by non-profit organisations or other research consortiums

Eligible research is designed, implemented and sponsored by independent clinical investigators, organisations or industry sponsors. Sensium does not design, conduct or supervise the study, but may provide support including scientific, technical, data analysis and training assistance related to Sensium technology.

Any investigators requesting research support from Sensium will serve as the sponsor of the proposed study. They will be expected to undertake the responsibilities of sponsorship as defined in the ICH Guidelines for Good Clinical Practice (GCP) and the European Clinical Trials Directive 2001/20/EC or United States Code of Federal Regulations (21 CFR) or regional regulatory equivalent. Sponsor responsibilities include, but are not limited to:

- Designing the protocol and conducting the scientific investigation
- Understanding and complying with any local regulatory requirements
- Monitoring the study
- Reporting safety data to regulatory authorities, the IRB/EC and Sensium as applicable
- Registering the study on a public website or any other venue required by law (e.g. www.clinicaltrials.gov)

Sensium will not agree to support any project without a thorough review of study-related materials and without proof that the research has been approved by the necessary regulatory bodies (e.g. IRC, EC, MHRA or equivalent as applicable). Upon review of the study materials Sensium may provide comments or suggested revisions as appropriate.

Sensium may support eligible studies by providing Sensium products at discounted rates and/or research funding, depending on the scope of the project. Sensium may also partner in research grant submissions to relevant funding bodies.

Submission and Review Process

Proposals for research should be submitted by downloading the Sensium Research Proposal Form available via the website, and emailing the completed form to research@sensium.co.uk

If you have any questions on completion of this form or would like more information on the product before submitting, please email research@sensium.co.uk

Sensium will acknowledge receipt of all research proposals via email.

A Sensium committee will review each submission. Decisions for support are made based on scientific merit as well as available resources and current company research priorities. Proposers should allow 3-4 weeks for initial review after a submission is received by Sensium.

A formal notification (approved or declined) will be provided once the research proposal has been reviewed.

Approved Proposals

When a research proposal is approved, the following information is needed from the investigator before formal study support can begin:

- Clinical Trial Supply Agreement, Purchase Order or equivalent agreement based on the scope of the project
- Verification of IRB/Ethics Committee approval or equivalent as applicable
- Final study protocol or synopsis (independent investigators and organisations)

Study Management

Sensium requires the sponsor to provide the following during the research duration:

- Timely requests for product delivery, training and other clinical/technical support
- Periodic study updates (enrolment progress, any changes to protocol or study timelines, planned publications etc)
- Reports of any adverse events or device malfunctions related to Sensium products.