

Investigator-Initiated Studies

Application Instructions

Step 1: Proposal Package

Submit an innovative research proposal to clinical@perimetermed.com that includes:

- Applicant information, including copy of Investigator Sponsor's signed and dated CV
- Study Proposal (Description of the clinical study)
 - Type of study
 - Proposed number of subjects
 - Potential study sites
 - Estimated study duration
 - Potential inclusion and exclusion criteria
 - Study endpoints and planned analysis
- Type of support requested by Perimeter (i.e., investigational device, consumables, OCT training and interpretation, financial assistance, etc.)
- Study Budget—If funding is being requested, submit a detailed description of the study costs. Any expenses that are not associated with the conduct of the study are strictly prohibited.

Each Proposal Package will be reviewed based on scientific merit and alignment with PMI's long-term business strategy. Applicants will be notified of the outcome, and those approved shall be invited to submit a Protocol Package. Approval of the proposal does not guarantee approval of the protocol or guarantee funding.

Step 2. Protocol Package

If your Proposal Package was approved and you are invited to submit a Protocol Package, submit a Protocol Package to clinical@perimetermed.com that includes:

- Study Protocol
 - Study title and rationale
 - Type of study
 - Number of subjects to be enrolled and number of study sites participating
 - Study duration
 - A description of the relevance of the clinical investigation in the context of the state of the art of clinical practice, if applicable
 - Information on subjects, inclusion and exclusion criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved in the study
 - Clinical and statistical endpoints, randomization, and blinding of subjects, if applicable
 - A description of necessary training and qualifications for the personnel involved in the study
- Statistical Analysis Plan (SAP)

All research proposals shall be assessed to ensure that they don't exceed fair market value (FMV). Funding requests for expenses not associated with study conduct are strictly prohibited.

After review of the Protocol Package, you will be notified whether or not your study is accepted into the Perimeter Medical Imaging Investigator-Initiated Study. If accepted, Perimeter will communicate details regarding next steps.