Investigator Initiated Study (IIS) Application Form



Application Form for Investigator Initiated Study (IIS) Funding/Product Support to include Clinical Investigation Plan (CIP) with rationale, objectives, design and pre-specified analysis, methodology, organisation, monitoring, conduct and record-keeping. Upon completion submit to iisapplications@coopervision.com for consideration by CooperVision, Inc.

Date	
Sponsor-Investigator and Principal Investigator	
names/contact details	
Institution details (if applicable)	
Study Title	
Background / rationale	
Primary study objectives / Hypothesis	
Primary Product (and use as per labelled indication)	
Study design	
Statistical analysis	
Test group / Control group	
Key inclusion / exclusion criteria; study population	
# investigational sites; subject sample size	
Procedures / Methodology	
Key variables	
Visit schedule	
Monitoring, conduct and record-keeping plans (as	
required for clinical investigations)	
Ethics (IRB) approval plans (if required)	
Any regulatory requirements	
Clinicaltrials.gov (or equivalent) registration (if required)	
Details of safety data and any AE reporting to	
Regulatory Body, Health Authority and CVI	
Timings (proposed study start and end date)	
Potential publication plan	
Support Requested (funding or product) – summary	
details	

DISCLOSURE: CooperVision, Inc. is committed to transparency in its interactions with eye care professionals and research/academic organisations/institutions. Consistent with applicable laws and/or codes of practice applicable to the medical device industry, certain information related to the project [including but not limited to, the names of the Parties, the amount of funding (including fees and expenses reimbursed) as well as the title and purpose of the agreement may be communicated to any relevant authorities/institutions and/or publicly disclosed by CVI and/or by its affiliated companies and/or by relevant authorities /institutions].

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