ESCRS RESEARCH GRANT AGREEMENT

This Research Funding Agreement (the "Agreement"), dated the _____ (the "**Execution Date**") is made by and between:

(1) The European Society of Cataract and Refractive Surgeons, a UK private limited company (company number 03153785) by guarantee without a share capital with its registered office at 5 Fleet Place, London, EC4M 7RD (hereinafter referred to as **"ESCRS"**).

And

(2) _____, represented by _____, (hereinafter referred to as **"XXXXXXXX"**) a _____ institution with an address at _____.

each, a "**Party**" and together the **"Parties"**

Recitals

WHEREAS ESCRS is a European clinical and scientific society of ophthalmologists with its main purposes are to promote education and research in the field of implant and refractive surgery, to advance and promote the study and practice of ophthalmology and research, to disseminate the useful results of such research and to promote experimental work in the field of intraocular lens implantation, refractive surgery and ocular medicine.

WHEREAS The_____ is proficient in the conduct of high quality basic, applied, clinical and surgical research in the field of ophthalmology.

WHEREAS The XXXXXXXX wishes to undertake an investigator-initiated clinical trial entitled: "_____" and ESCRS wishes to provide the XXXXXXXX with financial support in respect of under-taking and completing such work. For this clinical trial the EU Clinical trial regulation No 536/2014 will apply and the XXXXXXXX will overtake the tasks and responsibility of the legal Sponsor according to Art. 2 (2) no14.

WHEREAS The XXXXXXXX may invite other third parties to participate in such work and the XXXXXXXX shall be responsible for and shall co-ordinate the participation and engagement of any other parties.

WHEREAS ESCRS will provide financial support to the XXXXXXXX in respect of such work and the XXXXXXXX accepts such support on the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants herein set forth, the Parties hereby agree as follows:

1 DEFINITIONS

1.1 The following words and phrases have the following meanings:

"**Affiliate**" means any company or other entity that, directly or indirectly, controls, is controlled by or under common control with a Party. For these purposes, "control" shall include ownership of more than 50% of the voting stock of a company or other entity, and / or the legal power to direct the general management and / or to appoint more than half of the board of directors of another company or other entity.

"**Award**" means the funding provided by ESCRS, not to exceed a maximum value of €_____ (_____ euros) over the Term of this Agreement, to be used by the XXXXXXXX to conduct the Study, such amount to be inclusive of all costs and expenses of the XXXXXXXX, Chief Investigator, Principal Investigator(s) and Participating Institution(s) or Person(s) and inclusive of all relevant local or national taxes, VAT and insurances and all legal, consultancy, administrative, overhead or other associated expenses.

"**Budget**" means the defined costs and expenses required to complete the Study submitted by the XXXXXXXX, Chief Investigator and Principal Investigator(s)to the ESCRS, and included in Appendix 1.4.

"**Chief Investigator**" means the person with overall responsibility for the design, conduct, report and ICH-GCP obligations for the Study, including responsibilities for all sites and Principal Investigator(s). At the time of execution of this Agreement,_____, shall be the Chief Investigator and shall co-ordinate the work described in Appendix 1.1, on behalf of the XXXXXXXX and/or Chief Investigator, or any other person appointed by the XXXXXXXX in accordance with clause 2.3 as a replacement. At the time of execution of this Agreement, the Principal Investigator(s) are listed herein in Appendix 1.2. Prior to the Execution Date, the Principal Investigator(s) shall provide either a full-time employment of contract with the XXXXXXXX; or hold a formal research agreement between the XXXXXXXX and Participating Institution(s) or Person(s); or hold a consultancy agreement between a Principal Investigator(s) and with a Participating Institution(s) or Person(s), extending to the end of the Completion Date. The Principal Investigator(s) shall additionally provide ICH-GCP certification, either prior to the Execution Date, or within thirty (30) days after the Execution Date

"**Claim**" means any and all claims (whether successful or otherwise), loss, liability, damages of any nature, suits or proceedings brought in respect of personal injury or death or any other losses of whatsoever nature and/or associated expenses (including all professional fees, legal fees, expenses and other costs).

"**Completion Date**" means the date falling _____ months after the Study Start Date.

"**Confidential Information**" means all information, protocols, grant awards, budgets, inventions, data, intellectual property, scientific concepts, experiments, experimental designs, results, business or commercialization plans, in whatever form, including without limitation: verbal (if reduced to writing within 10 days of disclosure and marked "Confidential"), written, graphic, photographic, digital, recorded, prototype, sample and electronic of one Party (the "Disclosing Party"), that is directly or indirectly disclosed to the other Party (the "Receiving Party") in connection with or furtherance of the Research Project or this Agreement.

"**Data**" means any and all data, results and outcomes, in raw, analysed or other form, arising from the Study and collected by the XXXXXXXX and/or any Participating Institution(s) during or following performance of the Study.

"**Deliverables**" means the list of tasks and responsibilities outlined in Appendix 2 to be completed, discharged and delivered by the XXXXXXXX and the Chief Investigator.

"**Duration**" means a period of _____ months, starting on the Study Start Date.

"ESCRS Officer" means _____, Medevise Consulting SAS, Strasbourg, France who will support, collate and report the quarterly outcomes and performance of the Research Project described in Appendix 1.1 – 1.4, on behalf of the ESCRS. This officer may be changed over the course of the trial at the discretion of the ESCRS.

"**Ethics Committee**" means a committee that has been formally designated to approve, monitor, and review research involving humans with the aim of protecting the rights and welfare thereof in accordance with ICH E6 (R2) Good clinical practice (EMA).

"Funder" refers to the organization(s) that provide funding via a grant award for conduct of a clinical study.

"**Governing Law**" means any international, European Union and applicable local law , as well as generally accepted international conventions applicable to the performance of the Clinical Study. Such Law including but not limited to:

- Regulation (_____) of the European Parliament and the Council relating to and any implementation in Study Site's national Law (if applicable)
- the GDPR, and any applicable national implementing legislation,
- ICH-GCP (R2)Guideline and ICH E6 (R2) Good clinical practice— Good clinical practice
- the Declaration of Helsinki (2013),
- and/or any successors of the above-mentioned Laws.

"**Intellectual Property Rights**" or "IPR(s)" means all ownership and/or access rights in patents, patent applications, trademarks, trade names, trade secrets, know-how, service marks, domain names, copyrights, copyright applications, moral rights, rights in and to databases (including rights to extract information or prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or similar effect to any such rights which may subsist anywhere in the world, whether or not any such rights are registered and including applications for registration of such rights.

"**Know How**" means all data, technical and other information which is not in the public domain, including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by IPR(s) or applications for such rights, and which is required or necessary for the use or exploitation of IPR or Data.

"**Participating Institution(s) or Person(s)**" means such other institution(s) or person(s) as the XXXXXXXX may invite to participate, or which from time-to-time participates in the Study, including Principal Investigator(s), shall be to any one or more of such institutions and person(s)

and shall include representatives, officers, employees and directors of such Participating Institution(s) or Person(s).

"**Principal Investigator(s)**" means the person(s) who will lead the study team at the participating trial sites.

"**Product**" means any product, device, service, procedure, tool, software, device, diagnostic, process, intervention or medicinal product or medical service included, used or administered in the course of the Study or thereafter.

"**Qualifying Invoice**" means an invoice, on an *in-arrears* basis, issued by the XXXXXXXX to ESCRS, in a format acceptable to ESCRS, for the re-imbursement of eligible costs and expenses actually paid by the XXXXXXXX for the sole and exclusive purpose of conducting the Study in accordance with the Budget and supported by original valid evidence of expenditure, or such other documentary support, as may be requested by the ESCRS. Each Qualifying Invoice shall include (i) a clear statement recording the total Award amount remaining following payment for each invoice, (ii) a list of all payments previously received from ESCRS as of the invoice date (including their invoice number, amount and date), (iii) a detailed statement signed by the XXXXXXXX's Chief Investigator, and provided on the XXXXXXXX's headed institution paper, confirming that *all expenditure on the invoice is solely and exclusively incurred in direct support of the Study*, and; (iv) a detailed breakdown of each invoice amount into various expense categories as included in the appropriate table of the Budget (in Excel) included within Appendix 1.4.

"**Research Project**" means the body of work, including but not limited to the clinical trial, objectives, work packages, deliverables, design, methodology, statistical considerations and organization of, together with its successive versions and amendments (the most recent versions of which are set out on the Execution Date in this Agreement including: **Appendix 1.1** (ESCRS Grant Application Form), **Appendix 1.2** (list of Principal Investigator(s) and appropriate formal research agreements with Participating Institutions(s) or Person(s)), **Appendix 1.3** (Protocol) and **Appendix 1.4** (Budget, dated _____), all to be performed under this Agreement.

"Reporting" means the requirement of the Chief Investigator to provide a quarterly report on trial progress, along with budget update, to the ESCRS.

"**Site(s)**" means any clinical trial site used by the XXXXXXXX or a Participating Institution(s) or Person(s) as a site for the performance of work described in the Study.

"Sponsor" is the organization that accepts full responsibility and liability for the study conduct including the quality assurance measures to be put in place and followed for the duration of the study.

"**Study Start Date**" means [TBA 202X] as set out in Appendix 2.

"**Timelines**" means the dates set out in Appendix 2, as may be amended by written agreement between the Parties and Timeline shall mean any one of such dates.

"**Trial Master File (TMF)** or **electronic Trial Master File (eTMF)**" means the clinical trial master file (defined under relevant EU law), shall at all times, contain the essential documents relating to that clinical trial which allow verification of the conduct of a clinical trial and the quality of the data generated, taking into account all characteristics of the clinical trial.

1.2 References to "including" or "include" shall be construed without limitation.

1.3 Words denoting the singular include the plural, and vice versa.

1.4 References to clauses and appendices shall be to the clauses and appendices of this Agreement, unless otherwise stated. References to this "Agreement" shall include all appendices.

2 CHIEF INVESTIGATOR& ESCRS OFFICER

2.1 Prior to the Execution Date, the Chief Investigator must be engaged under a full-time contract of employment with the XXXXXXXX, or hold a consultancy agreement with the XXXXXXXX, extending to the Completion Date of the trial. The Chief Investigator shall additionally provide ICH-GCP certification, either prior to the Execution Date, or within thirty (30) days after the Execution Date.

2.2 The XXXXXXXX represents that it is entitled to procure and the XXXXXXXX shall procure, on or before the Execution Date, the full services of_____ to act as Chief Investigator and Principal Investigator of Cologne trial site and shall ensure the performance of the obligations allocated to the further participating Principal Investigator(s) under this Agreement.

2.3 The XXXXXXXX represents that the Chief Investigator is in good standing and has the necessary research experience and expertise to perform the research, as proposed in the Research Project detailed in Appendix 1.1,.

2.4 The XXXXXXXX shall notify ESCRS if the Chief Investigator ceases to be employed by, and/or formally affiliated with, the XXXXXXXX, and shall use its best endeavours to find a replacement Chief Investigator acceptable to both ESCRS and the XXXXXXXX. If no mutually acceptable replacement can be found ESCRS may terminate this Agreement pursuant to clause 14.4.

2.5 The ESCRS represents that it has procured the services of Medevise Consulting to act as the ESCRS Officer and shall ensure the performance of the obligations allocated to the ESCRS Officer under this Agreement.

3

PARTICIPATING INSTITUTION(S) S AND OTHER INVESTIGATORS

3.1 The XXXXXXXX shall ensure, and be directly responsible for, the performance of all obligations allocated to a Participating Institution(s) (s) or Person(s) in this Agreement.

3.2 Prior to the Study Start Date, the XXXXXXXX shall enter written contracts with each of the Participating Institution(s) (s) or Person(s) for the conduct of the Study on terms that (i) reflect the requirements of this Agreement and maintain rights equal to or greater than those rights provided by the XXXXXXXX to the ESCRS, including but not limited to the rights and obligations provided for in clause 5, 6, 7, 8, 9, 10, 11, 12 and 14, and; (ii) are customary for studies of the type contemplated in this Agreement. .

4

WARRANTIES OF THE XXXXXXXX

The XXXXXXXX warrants that:

4.1 it has full power and authority to execute, perform and deliver all obligations within the Agreement;

4.2 the Agreement is executed by its duly authorized representative with full legal and executive power and authority to do so;

4.3 it has obtained all necessary consents, approvals, authorizations, licenses and permissions which are required to enable it to comply with its obligations under the Agreement and will, throughout the duration of the Agreement, maintain all such consents, approvals, authorizations, licenses and permissions and shall not commit any act or omission which might invalidate, breach or otherwise impair the effect of such consents, approvals, authorizations, licenses or permissions;

4.4 every statement, representation or information provided in the Research Project and Budget, any documents furnished therewith, any report, IRAS form, TMF, Data or results or financial information is, to the best of the XXXXXXXX's and Chief Investigator's knowledge, true, complete and accurate;

4.5 the Budget submitted or agreed with the ESCRS comprises only eligible costs to be used solely and exclusively for the performance of the Research Project;

4.6 there is no other information of which the Chief Investigator the XXXXXXXX, or its agents are aware that is relevant to the Research Project or the interests of the ESCRS concerning the Research Project or the Agreement;

4.7 the Research Project will be performed with all due skill, care and diligence and by appropriately qualified personnel;

4.8 the Research Project shall be conducted in compliance with all applicable national or EU laws appropriate to the performance of a clinical trial and

4.9 the Research Project shall be conducted in accordance with such ethical guidelines as may be issued by the relevant EU and national authorities, or any relevant other regulatory body, from time to time, including (without limitation) guidelines relating to the conduct of trials which involve members of the public or samples taken from them. The XXXXXXXX further warrants that it shall comply with all obligations of and shall fulfill all responsibilities allocated under any and all relevant national and EU guidelines.

5 GOVERNANCE

5.1 The XXXXXXXX, as Sponsor, accepts sole responsibility for the conduct of the Study and acknowledges that ESCRS shall have no responsibility, obligation or liability, financial or otherwise, of any kind, to the XXXXXXXX or the Participating Institution(s) (s) or Person(s). Neither performance by ESCRS of any tasks allocated to ESCRS under this Agreement, nor any other provision of this Agreement, will be construed or interpreted to mean that ESCRS holds a XXXXXXXX role or obligation for this Study or is in any way responsible for the conduct, performance or safety of the Study.

5.2 Without prejudice to clause 5.1, the XXXXXXXX shall, and shall procure that the Chief Investigator, the Principal Investigator(s) and the Participating Institution(s) or Person(s) shall, conduct the Study in compliance with all laws and statutes applicable to the performance of the Study in the particular country of the Site(s), including those laws implementing the

European Convention on Human Rights, Regulation EC 2016/679 ("General Data Protection Regulation" or "GDPR"), and EU Regulation 2014/536, in addition to all relevant guidance relating to clinical trials from time to time in force. and the World Medical Association Declaration of Helsinki entitled "*Ethical Principles for Medical Research Involving Human Subjects*" (2013).

5.3 Should there be any express conflict between Appendix 1.1-1.3 and the other terms of this Agreement, the terms of Appendix 1.1-1.3 shall prevail to the extent such conflict relates to research and experimental design, including clinical safety issues. In respect of all other matters, including financial, reporting, legal, confidentiality and intellectual property, the terms of this Agreement shall prevail.

5.4 The XXXXXXXX shall keep ESCRS informed of the conduct and progress of the Study and its compliance with the Deliverables and Timelines through a written report (the "Quarterly Report") to be delivered on a quarterly basis to the ESCRS Officer within 21 days of each quarter day (January 1st, April 1st, July 1st and October 1st) for the Duration of the Agreement. Final reports shall be provided in accordance with clause 10.5. The Quarterly Report shall include a statement on the conduct and progress of the Research Project within each preceding quarter, together with a summary of the Deliverables and Timelines referable to the quarter. Any Deliverables or Timelines not achieved shall be addressed comprehensively within each such Quarterly Report, together with a correctional plan, if required, to ensure the Research Project remains on schedule for completion by the Completion Date. If so requested by the ESCRS Officer, the Chief Investigator and ESCRS Officer shall meet no less than once every quarter in person or by scheduled telecom at such times and venues as the Parties may mutually agree in order to facilitate XXXXXXXX providing such updates and progress reports.

5.5 The Parties agree that adherence to the Deliverables and Timelines set out in Appendix 2 is critical to the success of the Study and that all such Deliverables and Timelines shall be completed in full on or prior to the Completion Date. A failure to meet three (3) or more of the items outlined in the Deliverables and Timelines set out in Appendix 2 shall be deemed to constitute a material breach for which ESCRS may terminate this Agreement under clause 14.2. Any amendments to Deliverables or Timelines must be agreed in writing and signed by both Parties.

5.6 The XXXXXXXX as legal Sponsor of this clinical trial shall be responsible for:

5.6.1 the general design and conduct of the Study, including the preparation of all essential study documents, standard operating procedures, patient recruitment, data capture and collection forms, data management and storage systems, treatment protocols, statistical analyses and review, adverse event reporting, safety and all other management aspects related to the Research Project and the Agreement;

5.6.2 the review of all data collection practices and procedures as summarized in the Quarterly Reports and / or from visits to participating clinics or through other means to identify and correct remediable deficiencies;

5.6.3 the proactive consideration and adoption of changes in the study procedures, treatment protocol or experimental design as necessary and desirable during the course of the Study;

5.6.4 the appointment and disbandment of relevant committees if applicable and needed for execution of the Study;

5.6.5 the making of decisions on resource allocations and on priorities for meeting competing demands and obligations arising during the Study;

5.6.6 the review of progress of the Study in articulating and achieving its goals and objectives and taking all necessary steps required to enhance the likelihood of success in achieving such goals and objectives;

5.6.7 the consideration of recommendations for changes to the treatment protocol or experimental design, as may be identified from external treatment effects monitoring and review bodies;

5.6.8 the compliance of the Study with all regulatory and clinical practice obligations and guidelines as issued from time to time by national and EU responsible bodies.

6 OBLIGATIONS OF THE XXXXXXXX

6.1 The XXXXXXXX hereby agrees to (i) conduct and complete the Research Project, including all amendments approved by the relevant Ethics Committee or institutional review board and; (ii) the timely completion of all Deliverables, within the assigned delivery date, identified in Appendix 2.

6.2 The XXXXXXXX shall be responsible for obtaining and maintaining, and for ensuring that the Participating Institution(s) or Person(s) obtain and maintain any Study authorisation (if required) and all approvals from the relevant local research Ethics Committee(s) for the conduct of the Study at each Study Site. The XXXXXXXX shall keep ESCRS fully apprised of the progress of such submissions. Once the trial is approved, the XXXXXXXX shall provide ESCRS with a confirmation of approval.

6.3 The XXXXXXXX shall ensure that no changes are made to the Research Project at any Site in any country without the XXXXXXXX's prior written consent. The XXXXXXXX shall give ESCRS advance written notice of any proposed changes to the Research Project, as soon as reasonably possible after the XXXXXXXX identifies or becomes aware of such proposed changes.

6.4 The XXXXXXXX and the Chief Investigator shall ensure that the Participating Institution(s) (s) or Person(s)) conduct the Study in accordance with:

6.4.1 Appendix 1.1; and

6.4.2 any Study authorisation applicable to the Study; and

6.4.3 the terms and conditions of the approval)

and the XXXXXXXX shall ensure that no action mandated by the Research Project takes place in relation to any Deliverable or Timeline until it is satisfied that all relevant regulatory and Ethics Committee(s) approvals have been obtained.

6.5 The XXXXXXXX shall inform ESCRS immediately upon learning of the existence of any financial arrangement or interest between the Principal Investigator(s)or any Participating Institution(s) (s) or Person(s) and any commercial entity, pharmaceutical or research services or

consumables company, pharmacy or any other body with a potential vested or financial interest of the type described at paragraph (f) of Appendix 4.

6.6 If any Deliverable is significantly delayed (>1 month) (other than competent authority/ethics committee approval) according to the planned timelines at any Site, the XXXXXXXX shall instigate a correctional plan (within 30 days in writing) to compensate for the delay and inform the ESCRS of the delay in its quarterly reporting.

6.7 If the XXXXXXXX, Chief Investigator and/or Principal Investigator(s) reasonably believe there has been any research misconduct in relation to the Study, the XXXXXXXX, Chief Investigator and the Principal Investigator(s) shall identify the matter within 15 (fifteen) days in writing, and thereafter, conduct a thorough investigation into such alleged research misconduct and shall promptly report the findings thereof in writing to the ESCRS within 30 (thirty) days.

6.8 Neither the XXXXXXXX nor Chief Investigator nor the Principal Investigator, nor any Participating Institution(s) or Person(s) shall during the term of this Agreement conduct any other study that conflicts with the Research Project in accordance with this Agreement.

6.9 The XXXXXXXX and Chief Investigator shall be responsible for the management of the Participating Institution(s)/Sites or Person(s), including but not limited to the management of administrative, financial, ethical review, Study and relevant insurance and authorization documentation.

6.10 The XXXXXXXX and the Chief Investigator shall participate, in the promotion of the Study and ESCRS' grant, as may be requested from time to time by the ESCRS.

7 LIABILITIES, INDEMNITY AND INSURANCES

7.1 The XXXXXXXX shall fully defend, indemnify and hold harmless ESCRS, its Affiliates and their respective trustees, directors, employees, officers and agents, including all advisors, consultants and representatives of ESCRS (collectively, the "Indemnitees"), against any Claim suffered or incurred by ESCRS or any of the Indemnities and against any Claim resulting from or arising out of this Agreement or its performance or non-performance made or brought (whether successfully or otherwise):

7.1.1 by Participating Institution(s) (s) or Person(s), their Affiliates, employees, officers, representatives, product suppliers or any other third party;

7.1.2 by or on behalf of any XXXXXXXX employee, officer or agent, or any Study participant and (or their dependents) against ESCRS or any of the Indemnitees for personal injury, including death, arising out of or relating to any act required by the Research Project to which a potential claimant would not have been exposed but for their participation in the Study;

7.1.3 in respect of loss of or damage to property, or personal injury, including death, which is the result of administration or management by the XXXXXXXX of the Study, negligence on the part of the XXXXXXXX or of a breach by the XXXXXXXX of its obligations under this Agreement,

save to the extent that any such personal injury or loss or damage is the result of gross negligence on the part of ESCRS or any of the Indemnities.

7.2 XXXXXXXX shall provide a diligent defense against and/or settlement of any Claims brought or actions filed for the loss which is the subject of the foregoing indemnity, whether such Claims or actions are rightfully or wrongfully brought or filed.

7.3 XXXXXXXX hereby warrants and represents to ESCRS, from the Execution Date and for a period of 6 (six) years following the Completion Date of this Agreement, that it maintains an appropriate policy of insurance at levels sufficient to support the indemnification obligations assumed under this Agreement. XXXXXXXX shall provide evidence of such policy of insurance upon request. The XXXXXXXX further warrants and represents for the benefit of ESCRS that any shortfall that may arise between the XXXXXXXX's insurance cover and any payment, settlement or other similar award made in relation to any indemnification obligations of the XXXXXXXX, including any and all shortfalls that may arise from claims made in relation to a Principal Investigator, Participating Institution(s) (s) or Person(s), XXXXXXXX employee, Study participants or their dependents, shall be settled directly and in full by the XXXXXXXX to the satisfaction of the ESCRS.

7.4 For the purpose of the indemnity provided in clause 7.1 above, the expression "agents" shall include, but shall not be limited to, any person providing services to ESCRS under a contract for services or otherwise.

7.5 Nothing in this Agreement shall limit the liability of either Party for fraud, or limit the liability of either Party for death or personal injury resulting from such Party's negligence.

7.6 XXXXXXXX hereby warrants and represents to ESCRS, from the Execution Date and for a period of 6 (six) years following the Term of this Agreement, that it maintains an appropriate policy of insurance at levels sufficient to support the indemnification obligations assumed under this Agreement, in line with local requirements.

7.8 The insurances required to be obtained by the XXXXXXXX pursuant to the clause above shall not limit the obligations, liabilities or responsibilities of the XXXXXXXX under the Study or otherwise and the XXXXXXXX shall discharge all of its obligations which are insurable under the terms and conditions of this Agreement whether or not it has the requisite insurance or has received payment in respect of the insured obligations from its insurers.

7.9 The XXXXXXXX shall take out and maintain such medical malpractice insurance based on the required clinical trial coverage for its country or such similar cover as would be standard practice in the XXXXXXXX's jurisdiction, necessary to insure against liability for any claims, losses, damages and expenses (including legal and/or professional costs) due to the death or personal injury of any person arising as a result of or in connection with the Study and shall furnish to the ESCRS details of such policy on request. This insurance shall be maintained at all times by the XXXXXXXX for the Term and thereafter for a period of 6 (six) years.

7.10 The XXXXXXXX shall be liable to pay the full amount of any deductible or excess amounts arising under any insurance policies in respect of each and every claim.

7.11 The XXXXXXXX shall as soon as possible furnish to the ESCRS full details in writing of any event, occurrence or non-occurrence which is material to the indemnities and insurances provided for in this clause 7.

8 CONFIDENTIALITY

8.1 Medical Confidentiality

The Parties agree to adhere to the principles of medical confidentiality in relation to the Study. The XXXXXXXX shall not, and shall ensure that the Principal Investigators, Participating Institution(s) (s) or Person(s) shall not disclose personal data (as defined in the GDPR, including pseudonymized personal data which is capable of identifying the data subject) of Study participants to ESCRS, its Affiliates or any third parties save where this is required directly or indirectly for the purpose of adverse event reporting.

8.2 **Confidential Information**

8.2.1 The obligations of confidentiality set out in this clause 8.2.1 shall not apply to Confidential Information which is (i) published or generally available to the public through no fault of the Receiving Party, (ii) in the possession of the Receiving Party prior to the date of this Agreement, as evidenced by written records, and is not subject to a duty of confidentiality, (iii) independently developed by the Receiving Party, as evidenced by written records, and is not subject to a duty of confidentiality, or (iv) obtained by the Receiving Party from a third party not subject to a duty of confidentiality.

8.3 This clause 8 shall continue to apply after the expiration or termination of this Agreement.

8.4 For the purposes of this Agreement, Know-How and IPR owned, assigned or licensed to the XXXXXXXX prior to the Execution Date and capable of exploitation independent of Data or Confidential Information arising through the performance of the Research Project, shall be deemed to be XXXXXXXX's Confidential Information (and XXXXXXXX shall be deemed the Disclosing Party of such information).

9 PUBLICITY

9.1 The XXXXXXXX will not use the name of the ESCRS, nor of any member of the ESCRS's trustees, directors, staff, agents or representatives, in any publicity, advertising or news release without the prior written approval of an authorised representative of the ESCRS, such approval not to be unreasonably withheld by the ESCRS.

9.2 Subject to clause 8, ESCRS shall be entitled to use the results generated under the Study for the purpose of publicizing ESCRS' grant to the XXXXXXXX and the XXXXXXXX shall participate in all such publicity or marketing initiatives of the ESCRS.

9.3 XXXXXXXX shall not, and shall ensure that Participating Institution(s) (s) or Person(s) and XXXXXXXX personnel, including Chief Investigator and Principal Investigators do not engage in interviews or other contacts with the media, including but not limited to newspapers, journals, radio, television, blogs, social media or any internet based media, related to the Study, the Research Project, Data or IPR without the prior written consent of ESCRS. This provision does not prohibit publication or presentation of Data in accordance with clause 10 herein.

10 DELIVERY OF DATA

10.1 The XXXXXXXX will collect the results of the Study from its Site(s) and will provide interim, if included in the study plan, and final clinical study reports.

10.2 Without prejudice to clause 10, and subject to clause 11, the XXXXXXXX shall not, and shall ensure that the Participating Institution(s) (s) or Person(s) shall not, give access to the Data to any company, organization or institute other than ESCRS (or ESCRS's nominees) during the term of this Agreement and for a period of five (5) years from the date of termination of this Agreement, unless otherwise agreed in writing, or ii) required pursuant to applicable law, or iii) to a service provider to the extent required for the purpose of the Study and/or data management.

10.3 After completion of the final statistical analysis of the Study (whether prematurely or otherwise) the XXXXXXXX shall provide ESCRS with a comprehensive report of the Study detailing all methodology, data and results and containing an analysis of the Data and drawing appropriate conclusions within 30 (thirty) days of report finalization.

10.4 The XXXXXXXX shall ensure that the Data are kept for the appropriate length of time and in orderly, safe and secure storage in accordance with regulatory requirements for document retention.

11 PUBLICATION

11.1 ESCRS recognizes that the XXXXXXXX and Chief Investigator intend that results of scientific interest arising from the Study will be appropriately published and disseminated. ESCRS agrees that employees of the XXXXXXXX and of the Participating sites shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise, methods and results of the Study subject to clauses 11.2 and 11.3.

11.2 The objective of clinical research is to disseminate the results and information to patients, to the professional ophthalmic community and the public, under-written by an independent peer-review process. The ESCRS requires that recipients of its research awards adhere to this objective by publishing the results of research and/or studies that have been funded by the society.

As a first preference, award recipients should consider submission to the ESCRS journal, the Journal of Cataract & Refractive Surgery. However, award recipients are able to submit their manuscript(s) to an appropriate ophthalmic journal, if they prefer not to submit to JCRS.

A key requirement of publication is to enable open access to the publication in order to ensure the widest possible dissemination of the results. Award recipients should also plan to submit the results of their research to two ESCRS meetings for scientific presentations.

The award recipient(s) agree to submit the draft of publication(s) for review by a member of the ESCRS Clinical Research review panel ahead of submission to the target publication. (The ESCRS Clinical Research team will assign a reviewer based on topic.)

11.3 All original, peer-reviewed research articles that recipients have developed as part of an ESCRS research award must:

11.3.1 Ensure that the publication is made freely available through PubMed Central (PMC) and Europe PMC by the official final publication date, and;

11.3.2 Is published under a Creative Commons attribution licence (CC BY), unless ESCRS has agreed to an exception, to allow publication under a CC BY-ND licence.

11.3.3 Where there are multiple institutions involved in the publication, all research articles must be compliant with this policy.

11.3.4 All publications resulting from ESCRS-funded research must contain the following statement:

'This research was funded in whole by the European Society of Cataract & Refractive Surgeons (ESCRS). For the purpose of open access, the author has applied a CC BY public copyright licence to any Author Accepted Manuscript version arising from this submission.'

12 INTELLECTUAL PROPERTY

12.1 Any Intellectual Property Rights created or developed in the course of the Study between the Parties remain with the XXXXXXXX.

12.2 The XXXXXXXX shall inform ESCRS of any Intellectual Property Rights created or made in the course of the Study in a timely manner and shall consult with ESCRS as to the filing of any patent or other protections for such Intellectual Property Rights.

12.3 The XXXXXXXX must obtain the ESCRS's written consent *before* entering into any transactions to assign, license, develop or commercialise any Intellectual Property Rights created or developed in the course of the Study which consent may be subject to the Parties entering into an agreement including terms and conditions relating to a financial return for ESCRS in accordance with ESCRS Intellectual Property Policy (attached at Appendix X). In the *Invitation to submit a full Grant Application – TBA ESCRS Clinical Research Awards, dated TBA*, the Chief Investigator hereby confirms the acceptance of the ESCRS Guidelines and the "Principle Terms Agreement", enclosed.

12.4 The XXXXXXXX warrants to and undertakes with ESCRS that it shall not infringe the Intellectual Property Policy of any third party in the course of the Study.

12.5 The XXXXXXXX and the Chief Investigator hereby confirm the acceptance of the "ESCRS Intellectual Property Policy" (enclosed in Appendix X).

13 FINANCIAL ARRANGEMENTS

13.1 Subject to the compliance of the XXXXXXXX and the Chief Investigator with the terms and conditions of this Agreement and subject to the completion of the required Deliverables and objectives as set out in Appendix 2, ESCRS shall support the Study through the provision of the Award. Payment of the Award, or any part thereof, shall be subject at all times to the satisfactory delivery of Quarterly Reports in a timely manner and subject to the periodic review of Data and Study progress by the Chair of the ESCRS Research Committee and subject to the XXXXXXXX's compliance with the terms of the Agreement. Where the Award is apportioned over specific objectives or timelines, all subsequent payments shall be made subject to the delivery of the relevant objectives within the designated timelines.

13.2 Within 60 (sixty) days of the execution of this Agreement and following receipt of an invoice from TBA on behalf of the XXXXXXXX in a format acceptable to ESCRS, ESCRS shall pay to the

XXXXXXXX, by electronic funds transfer, an initial payment of [€xx] of the Award. Following this initial payment, the recipient must submit with subsequent invoices, all of the expense, documentation, receipts and disbursements. All funds shall be designated in Euros (€), unless otherwise agreed, and all banking fees, transfer or other similar bank charges shall be borne directly by the XXXXXXXX.

13.3 In arrears and on a quarterly basis, XXXXXXXX shall submit a Qualifying Invoice for the previous quarter period which, if approved by ESCRS, will be paid to the XXXXXXXX by electronic funds transfer as designated in Appendix 3.

13.4 If the costs incurred by the XXXXXXXX in carrying out the Study exceed the amount of the Award such excess shall be borne by the XXXXXXXX. If the costs incurred by the XXXXXXXX in carrying out the Study amount to less than the Award, ESCRS shall be obliged to pay only such amount as may be necessary to discharge actual incurred and eligible costs.

13.5 No monies provided by ESCRS as part of the Award may be used by the XXXXXXXX to cover overhead or administrative costs other than those specifically identified and provided for in the Budget included in Appendix 1.1. Under no circumstances shall the maximum allowable overheads exceed **2.0%** (two percent) of the total Award over the Term of the Agreement.

13.6 Any costs or expenditure incurred prior to the Execution Date shall not be eligible for re-imbursement from the Award, unless otherwise agreed in writing between the Parties.

13.7 .

14 TERM AND TERMINATION

14.1 This Agreement will remain in effect from the Execution Date until the later of (i) fifteen (15) months from the Execution Date or, (ii) Completion Date of the Study, close-out of the Site(s) and completion of the obligations of the Parties under this Agreement (the "**Term**"), or earlier termination in accordance with this Agreement.

14.2 ESCRS (the "**Terminating Party"**) may terminate this Agreement with immediate effect at any time if the other Party (the **"Defaulting Party"**):

14.2.1 is in material breach of any of the Defaulting Party's obligations under this Agreement and fails to remedy such breach where it is capable of remedy within thirty (30) days of a written notice from the Terminating Party specifying the breach and requiring its remedy;

14.2.2 is declared insolvent; or, becomes involved in any litigation regarding breach of statutory company obligations; or, is found guilty of any criminal offence; or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business;

14.2.3 if the XXXXXXXX should fail to initiate, progress or complete the Study to the satisfaction of ESCRS without reasonable cause.

14.3 A Party may terminate this Agreement on notice to the other Party with immediate effect if it is reasonably of the opinion that the Study should cease in the interests of the general health or safety of Study participants involved in the Study.

14.4 ESCRS may terminate this Agreement on notice to the XXXXXXXX if the Chief Investigator is no longer able (for whatsoever reason) to act as Chief Investigator and no replacement mutually acceptable to the XXXXXXXX and ESCRS can be found within a reasonable period of time, not to exceed a duration of thirty (30) days from the date on which TBA becomes no longer able to act as Chief Investigator.

14.5 S.

14.6 In the event of early termination of this Agreement by ESCRS, the provisions of clause 9.2, 10, 11.2 and 12 may be applied immediately at ESCRS' sole discretion.

14.7 Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement. For the avoidance of doubt, upon termination of this Agreement, ESCRS shall have no obligation to provide any further funding of any nature whatsoever.

14.8 If termination of this Agreement arises from the provisions of clause 14.3, 14.4 or 14.5 then there shall be no liability on the part of ESCRS to the XXXXXXXX, save and except for the payment of outstanding amounts due to the XXXXXXXX by ESCRS up to the date of termination and in relation to which the XXXXXXXX is unable to secure refunds or cancellation of qualifying expenditure.

14.9 If termination of this Agreement arises from the provisions of either clause 14.2 or 14.6 then ESCRS shall be entitled to seek on demand the repayment of all sums paid in respect of the Award. In default of such repayments all such sums shall be recoverable by ESCRS, or its nominee(s), as a simple contract debt.

14.10 Expiration or termination of the Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination, and the provisions of clause 3, 4, 5, 6, 7, 9, 11-13 inclusive and clause 15 of this Agreement shall survive expiration or termination.

15 RELATIONSHIP BETWEEN THE PARTIES

15.1 Subject to clause 15.2, neither Party may assign its rights under this Agreement or any part thereof without the prior written consent of the other Party and neither Party may sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Party. Any party who so sub-contracts shall be responsible for the acts and omissions of its sub-contractors as though they were its own. ESCRS expressly consents to the performance of (i) contract and budget management (ii) data management (iii) monitoring (iv) project management by TBA on behalf of the XXXXXXXX.

15.2 .

15.3 Nothing in this Agreement shall be construed as creating a partnership, contract of employment or relationship of principal and agent between the Parties.

16 AGREEMENT AND MODIFICATION

16.1 Any change in the terms of this Agreement shall be valid only if the change is made in writing and is agreed and signed by the duly authorized officers of both Parties.

16.2 This Agreement contains the entire understanding between the Parties and supersedes all other negotiations, communications, principle terms, representations and undertakings, whether written or oral, of prior date between the Parties relating to the Study.

17 FORCE MAJEURE

Neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or due to any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance, and such notification shall include a detailed description of the nature of such delay or failure. In the event of such delay or failure lasting for three (3) months or more the non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the other Party.

18 NOTICES

Any notices under this Agreement shall be in writing, signed by the relevant Party to this Agreement and delivered personally, by courier, by recorded delivery post or by e-mail.

Notices to ESCRS shall be addressed to:

Notices to the XXXXXXXX shall be addressed to:

_____**PI Name**

Institution
Address 1
Address 2
Country Postcode
e-mail:

Legal and financial notices to the ESCRS shall be addressed to:

Gilly Burgess
Finance Director
European Society of Cataract & Refractive Surgeons
5 Fleet Place, London, EC4M 7RD
United Kingdom

19 RIGHTS OF THIRD PARTIES

Nothing in this Agreement is intended to confer on any person who is not a Party any right to enforce any term of this Agreement except that Affiliates of ESCRS may enforce the provisions of this Agreement that directly address them.

20 WAIVER

20.1 No failure, delay, relaxation or indulgence by any Party in exercising any right conferred on such Party by this Agreement shall operate as a waiver of such right, nor shall any single or partial exercise of any such right nor any single failure to do so, preclude any other or future exercise of it, or the exercise of any other right under this Agreement.

21 DISPUTE RESOLUTION

21.1 The Parties shall use their reasonable endeavours to resolve any dispute arising out of or in connection with any provision of this Agreement (a "**Dispute**") by good faith negotiations. In the event that the Dispute is not resolved, then either Party may at any time provide written notification to the other Party of the substance of such Dispute and the Parties agree to use their best endeavours to field appropriate representatives to participate in a face-to-face meeting to be held no later than thirty (30) days after receipt of such notice by the receiving Party.

21.2 If the Dispute has not been resolved during the meeting set out in clause 21.1, the Dispute shall be referred to the appropriate senior management representatives of each Party for resolution.

21.3 If the Dispute has not been resolved by the senior representatives of each Party within thirty (30) days after the face-to-face meeting of such representatives (or such other timeframe as may be agreed between the Parties), then either Party may refer the matter to the Courts of England.

22 GOVERNING LAW

22.1 The laws of _____ shall govern the validity, constructions and performance of this Agreement. Any dispute arising under, or in connection with, this Agreement shall be subject to the non-exclusive jurisdiction of the to which the Parties to this Agreement hereby submit.

22.2 This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

Executed by the duly authorized representatives of the Parties on the Execution Date

Signed on behalf of **European Society of Cataract and Refractive Surgeons.**

Name:

Title:

Signature:

Date: _____

Signed by the legally designated signatory on behalf of the **XXXXXXXX**

Name: _____

Title: _____

Signature: _____

Date: _____

Acknowledged, understood and agreed by the **Chief Investigator**

Name: _____

Title: _____

Signature: _____

Date: _____

Acknowledged, understood and agreed by the _____

Name: _____

Title: _____

Signature: _____

Date: _____

APPENDIX 1.1 – REVISED RESEARCH PROJECT (*TBA*)

Title: TBA

Insert Word copy grant application as provided on short-listed [date]

APPENDIX 1.2 – PRINCIPAL INVESTIGATOR(S) List of Investigators with the following details:

Name:

Work Address:

APPENDIX 1.3 – Protocol

APPENDIX 1.4 – Budget

APPENDIX 2 –DELIVERABLES AND TIMELINES

Roles and Responsibilities of XXXXXXXX:

The following table sets out the respective responsibilities for the Study, the Chief Investigator; all deliverables and documents shall be submitted contemporaneously in copy (cc) to the ESCRS Officer:

A	XXXXXXXX & Participating Institution(s) Sites	XXXXX XXX	ESCRS	Notes	Timelines
1	Submit a full and detailed GANTT file (on Excel) for the entire Study from Execution Date to Completion Date; Submit Participating Institution(s) Site List	✓			include GANTT within 30 (thirty) days of the Execution Date;
2	Approval of Final Investigator Site List	✓			Protocol
3	Notification to Trial Sites of their inclusion/ exclusion into the Study	✓			To be confirmed by XXXXXXXX prior to execution agreement
4	Site assessment and study initiation visits at each Trial Site; notify all Site, Interim and Closing meetings within 30 (thirty) days of the date / time / location	✓			To be confirmed by XXXXXXXX prior to execution agreement
	Establish the TMF at least 30 (thirty) days before site initiation visits	✓			
6	Study specific training for Trial Site personnel	✓			To be confirmed by XXXXXXXX prior to execution agreement
7	Routine Trial Site monitoring	✓			Ongoing
8	Scheduling of study open/ close-out / termination visits at each Trial Site	✓			Ongoing
9	Execution & Administration of Participating Institution(s) s Agreements	✓			To be confirmed by XXXXXXXX prior to execution agreement
10	Administration of payments to XXXXXXXX on foot of Qualifying Invoices	✓	✓	(1)	Ongoing
11	Administration of Participating Institution(s) s payments	✓			Ongoing
B	**Regulatory Ethics Committee Submissions & Approvals**	**XXXXX XXX**	**ESCRS**	**Notes**	**Timelines**

1	Submission for and provision of ethics and regulatory approval	✓			To be confirmed by XXXXXXXX prior to execution agreement
2	Provision of required Study documentation in sufficient quantities for all Participating Institution(s) s	✓			To be confirmed by XXXXXXXX prior to execution agreement
3	Provision of Principal Investigators	✓			To be confirmed by XXXXXXXX prior to execution agreement
4	Registration of the Study with an appropriate protocol registration scheme	✓		(2)	To be confirmed by XXXXXXXX prior to execution agreement
5	Participating Institution(s) s / Hospital administration submission(s)	✓			To be confirmed by XXXXXXXX prior to execution agreement
6	Response to queries raised at Submission meetings	✓			If required, ASAP after receiving queries
7	Submission for approval and notification of Protocol Amendment	✓			If required
8	Approval to start Recruitment at each site	✓		(2)	As soon as all required approvals are obtained and confirmed to ESCRS
9	Distribution of approval/notification documentation to each Trial Site	✓			As soon as all required approvals are obtained and confirmed to ESCRS
D	**Study Conduct**	**XXXXX XXX**	**ESCRS**	**Notes**	**Timelines**
1	Kick-off meeting Quarterly Reports to be delivered to ESCRS on each quarter day in accordance with clause 5.4, beginning QX-202X throughout term of Agreement	✓	✓		To be confirmed by XXXXXXXX
2	Recruitment planning	✓		(3)	Ongoing
3	Recruitment management	✓		(3)	Ongoing

4	Recruitment tracking updates	✓	✓	(3)	Ongoing
5	Study specific Trial Site audits on Sponsor's decision	✓			Ongoing
6	Provision of adverse event/serious adverse event reporting procedures and handling of events	✓			Ongoing
7	Provision of and training on specialised Study equipment	✓			Ongoing
8	Reporting of serious adverse events to Ethics Committees	✓			Ongoing
9	Reporting of serious adverse events to Regulatory Authorities	✓			Ongoing
11	Data Query Return	✓			Ongoing
E	**Study Documentation**	**XXXXX XXX**	**ESCRS**	**Notes**	**Timelines**
1	Design of Case Report Forms and database; data entry, management and monitoring; provision of centralised IT resource for data collection	✓			To be confirmed by XXXXXXXX
2	Provision of Protocol and Amendments to all Participating Institution(s)	✓			As applicable
3	Provision of Study-specific indemnity arrangements to Trial Sites	✓			Prior to recruitment start
4	Provision of Case Report Forms	✓			Prior to recruitment start
5	Provision of written patient information / consent form	✓			Prior to recruitment start
7	Collection of signed and dated, updated CVs for all study personnel.	✓			Prior to recruitment start
8	Review of each Suspected Unexpected Serious adverse reaction (SUSAR).	✓			Ongoing
F	**After the Study**	**XXXXX XXX**	**ESCRS**	**Notes**	**Timelines**
1	Control of Case Report Forms and return of Case Report Forms	✓			Ongoing when patient complete
2	Notification to Ethics Committee of Study completion / termination	✓			When milestone reached
3	Publications	✓			To be confirmed by XXXXXXXX

4	Archiving of the XXXXXXXX study documents with secure access provided to Participating Institution(s) s and ESCRS	✓			When trial closed
5	Archiving of Trial Site Study documents	✓			When trial closed
6	Preparation of Study Report	✓			To be confirmed by XXXXXXXX
7	Close out meeting	✓			When trial closed
G		**XXXXX XXX**	**ESCRS**	**Notes**	**Timelines**
1	Telephone meetings between sites (as ESCRS requested)	✓	✓		Ongoing
2	Face to face (online) meetings between project manager and ESCRS - max of 1 every 6 months	✓	✓		Ongoing

Notes:

(1) Support will be in the form of electronic fund transfer to the designated bank account of the XXXXXXXX.

(2) Recruitment will only begin following receipt of written Participating Institution(s) 's / Hospital approval and confirmation from the XXXXXXXX that recruitment can commence.

(3) If recruitment is delayed at any trial site, the XXXXXXXX shall instigate a correctional plan to make up for the recruitment shortfall at that Trial Site.

Additional Notes

a. **Pharmacy Arrangements -** will be organised by XXXXXXXX at the XXXXXXXX's own cost.
b. **Audit** - Any Trial Site may be subject to audit by the XXXXXXXX as the legal Sponsor or the Regulatory Authorities

APPENDIX 3 – FINANCIAL PAYMENT ARRANGEMENTS

This Appendix specifies the electronic fund transfer details of the XXXXXXXX, confirmed by the XXXXXXXX, as follows.

XXXXXXXX bank details	**Payment reference**	**Estimated Payments**
Name and address of bank: TBA IBAN:TBA BIC: TBA Reference on payments: TBA Other: Contact person: TBA E-mail: TBA	Each payment should include the Qualifying Invoice reference number and the reference " Dr. TBA"	**First payment – upon execution as per clause 13.2** Subsequent payments to the maximum amount of the Award, whichever the case may be, to be made in accordance with clause 13

APPENDIX 4 - CONDITIONS APPLICABLE TO THE PRINCIPAL INVESTIGATOR(S)AND PARTICIPATING INSTITUTION(S) (S) OR PERSON(S)

(a) The Principal Investigator(s)and the Participating Institution(s) (s) or Person(s) are free to participate in the Study and there are no rights which may be exercised by, or obligations owed to, any third party which might prevent or restrict performance of the obligations detailed in this Agreement.

(b) The Principal Investigator(s)and the Participating Institution(s) (s) or Person(s) are not involved in any regulatory or misconduct litigation or investigation by an employer, the European Medicines Evaluation Agency, the Food and Drug Administration, the Medicines Control Agency, the General Medical Council, UK Medical Council or other regulatory or similar authorities. No data produced by the XXXXXXXX or the Principal Investigator(s)and the Participating Institution(s) or Person(s) in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

(c) The Principal Investigator(s) and the Participating Institution(s) (s) or Person(s) have considered, and are satisfied that, facilities appropriate to the Study are available at all Sites and that the Study is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the XXXXXXXX and the Chief Investigator to perform the Study efficiently and in accordance with all obligations under the Agreement.

(d) The Principal Investigator(s) and the Participating Institution(s) (s) or Person(s) carry an appropriate level of medical liability insurance or the XXXXXXXX carry a medical liability insurance covering the Principal Investigator(s) and Participating Person(s) and all other personnel involved in the Study) and details and evidence of the coverage will be provided to ESCRS upon request.

(e) .

(f) .

APPENDIX 5 – INTELLECTUAL PROPERTY RIGHTS AND KNOW-HOW OWNED BY OR LICENSED TO THE XXXXXXXX, PARTICIPATING INSTITUTION(S) OR OTHER INVESTIGATORS (IF APPLICABLE)

ONLY COMPLETE THIS APPENDIX IF THERE IS SPECIFIC IPR YOU WISH TO IDENTIFY ON OR BEFORE THE EXECUTION DATE

APPENDIX X – ESCRS INTELLECTUAL PROPERTY POLICY

As a not-for-profit organization, the ESCRS endeavors to ensure that the research that it funds benefits the ophthalmic community, as well as patients.

The intent of the ESCRS Intellectual Property Policy is to foster an environment that serves as a catalyst for clinicians and researchers to develop innovative products and technologies that lead to breakthroughs and improvements in eye care. In addition, it is intended to clearly set out expectations on the part of the society related to any intellectual property (IP) that results from awards that it has granted, as well as to simplify the process for clinicians and researchers.

Policy Overview

As a not-for-profit organization, the ESCRS must ensure that the results of the funded research meet the requirements stated above. At the start of a research project, it may not be known if some type of intellectual property (IP) will be the result of the work that has been funded, but might involve:

- Translating inventions into new treatments which benefit patients directly.
- The development and dissemination of new research tools, software and materials, to help the research or translational efforts of others.

At a minimum, ESCRS expects that the results of all funded research will be peer-review published and freely disseminated through scholarly journals. In the event that an ESCRS-funded research grant results in a more tangible, i.e., IP that may be patented and/or commercialized, this policy sets out the ESCRS's position with respect to revenue and equity sharing, and consent when commercialising such IP.

Additionally, the ESCRS has an obligation to ensure that private benefits arising from its funding, such as wealth creation, are acceptable. To meet this obligation, the society will take a share of any revenue and equity that the ESCRS research award holders generate as a result of ESCRS-funded IP. This income will be used to fund further awards. To strike a balance between incentivising researchers, as well as to support the awards programme, the ESCRS will take a flat rate of revenue and/or equity share of 25 per cent, to be capped at the full amount of the ESCRS award grant.

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Policy statement

1. All award holders must obtain the ESCRS's written consent *before* entering into transactions to develop or commercialise ESCRS-funded IP. An exception is granted for not-for-profit universities and research institutes, where consent will be given retrospectively, when the institution reports the commercialisation to ESCRS. The ESCRS will keep this waiver under review, and it may be modified or withdrawn at any time. For it to continue, an organisation must:
    - Adhere to the intellectual property policy
    - Report any IP-related activities to the ESCRS on an annual basis

2. This policy applies to all forms of IP, including:

- Copyright in software
- Database rights in large datasets
- Rights in designs, e.g., for new equipment
- Rights in confidential know how.

3. Persons applying for ESCRS research grant funding should consider and anticipate at the application stage the management and sharing of any output (as described in point 1) that results from their work.

In instances where these outputs are thought to be significant – e.g., patentable inventions, large databases, substantial pieces of software or new research materials, such as antibodies, cell lines or animal models – applicants will need to include a statement explaining their planned approach to the IP arising from the research. This will be considered as part of the funding decision.

4. Researchers can use part of their awards funding to cover the initial costs of protecting patents and registering designs. After this, their employers are responsible for all additional costs of protecting, maintaining and commercialising that IP throughout its lifetime.

5. ESCRS-funded IP must not be used only to block further research and development by others, either actively or passively. The society expects registered IP to be abandoned if there is no credible plan to commercialise it and if it presents a barrier to other researchers.

6. Funded organisations will need to complete and submit an annual report to the ESCRS Research Committee each year that includes any IP activity.