IRB-SOP-016（F）-002-03

伦理审查批件

批件号：2021-004-01

<table>
<tr><td>项目名称</td><td colspan="4">眼科多模态影像处理的相关算法研究</td></tr>
<tr><td>项目来源</td><td colspan="4">/</td></tr>
<tr><td>项目负责人</td><td>黄丽娜</td><td>所在科室</td><td colspan="2">青光眼科</td></tr>
<tr><td>审查文件</td><td colspan="4">研究方案（版本号：v3　版本日期：2021.11.14）
知情同意书（版本号：v2　版本日期 ：2021.11.8）</td></tr>
<tr><td>审查类别</td><td colspan="4">☑初始审查　☐跟踪审查　☐复审</td></tr>
<tr><td>审查方式</td><td colspan="4">☐会议审查　☑简易审查　☐紧急会议审查</td></tr>
<tr><td>会议日期</td><td colspan="2"></td><td>审查会议地点</td><td></td></tr>
<tr><td rowspan="3">投票结果</td><td colspan="4">共有委员___名，实到___名，投票___名，回避___名</td></tr>
<tr><td>同意___票</td><td colspan="3">作必要修改后同意__票</td></tr>
<tr><td>不同意___票</td><td colspan="3">暂停或者终止已同意的研究___票</td></tr>
<tr><td rowspan="2">审查意见</td><td colspan="4">审查决定：眼科多模态影像处理的相关算法研究</td></tr>
<tr><td colspan="4">根据《药物临床试验质量管理规范》（2020 年）、《医疗器械临床试验质量管理规范》（2016 年）、《药物临床试验伦理审查工作指导原则》（2010 年），《涉及人的临床研究伦理审查委员会建设指南（2020 版）》、《涉及人的生物医学研究伦理审查办法》（2016 年）、《药物临床试验质量管理规范》（2003 年）、CFDA《药物临床试验伦理审查工作指导原则》（2010 年）、《赫尔辛基宣言》和《人体生物医学研究国际道德指南》的伦理原则。经本伦理委员会审查同意按所同意的临床研究方案、知情同意书开展本项研究。
注：
1、请遵循 GCP 原则、遵循伦理委员会同意的方案开展临床研究，保护受试者的健康和权利。2、对研究方案、知情同意书、招募材料等的任何修改，请提交修正案审查申请。3、发生 SAE，请及时提交严重不良事件报告。4、如有不依从/违背方案的情况，请及时提交不依从/违背方案报告。5、请根据年度/定期跟踪审查频率，及时提交研究进展报告。6、暂停或提前终止临床研究，请及时提交暂停/终止研究报告。7、完成临床研究，请提交结题报告。</td></tr>
<tr><td>年度定期/跟踪审查频率</td><td>6 个月</td><td>批件有效期</td><td colspan="2">1 年（2021.11.15-2022.11.14）
（请在批件到期前一个月提交跟踪审查申请）</td></tr>
<tr><td>联系人</td><td>何芬</td><td>联系电话</td><td colspan="2">15802853561</td></tr>
<tr><td>主任委员（被授权者）签名</td><td colspan="4">伦理委员会（盖章）
2021 年 11 月 17 日</td></tr>
</table>

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ETHICAL REVIEW APPROVAL

Approve No.2021-004-01

Topic of the Project	Research on related algorithms of ophthalmic multimodal image processing	
Project resource	/	
Project manager	Lina Huang	Department Glaucoma Department
Review documents	Project document Informed consent	V3 (2021.11.14) V2 (2021.11.8)
Review category	Initial review	
Review method	Summary review	

Decision

According to the code for quality management of clinical trials of drugs (2020), the code for quality management of clinical trials of medical devices (2016), the guiding principles for ethical review of clinical trials of drugs (2010), the guidelines for the construction of Ethical Review Committee for clinical research involving people (2020 Edition), and the ethical review measures for bovine and physical research involving people (2016) , the code for quality management of drug clinical trials (2003), CFDA guiding principles for ethical review of drug clinical trials (2010), Declaration of Helsinki and the international ethical guide for human biomedical research. After review by the ethics committee, it is agreed to carry out the study according to the agreed clinical research scheme and informed consent.

Remarks:

1. Please follow the principles of GCP and the protocol agreed by the ethics committee to carry out clinical research and protect the subject's health and rights. 2. For any modification of the research protocol, informed consent, recruitment materials, etc., please submit an application for amendment review. 3. In case of SAE, please submit the defective parts report in time. 4. In case of non-compliance / violation of the scheme, please submit the non-compliance / violation report in time. 5. Please submit the research progress report in time according to the annual / regular follow-up review frequency. 6. If the clinical study is suspended or terminated in advance, please submit the suspension / termination report in time. 7. After completing the clinical study, please submit the conclusion report.

Annual periodic / follow-up review frequency: 7 Monthes

term of validity:2021.11.15-2022.11.14

contacts: Fang He

Mobile: 15802853561

Signature of chairman (authorized person)

数据使用授权及医学数据伦理说明

本单位授权澳门城市大学数据科学研究院王涵博士（身份证号：410802199402070065，学号：D20092100037），针对“人工智能在眼科领域中的应用”及其相关研究项目，合理合规使用本单位提供的数据进行科学研究相关工作。

本单位承诺，上述授权数据符合中国生物医学伦理审查制度。

承诺单位：

日期：2021 年 8 月 18 日

DATA ACCESS AUTHORIZATION & MEDICAL DATA ETHICS SUPPORTING

We authorized the data access to Han Wang, the Ph.D from Institute of Data Science, City University of Macao (Id Number: 410802199402070065, Student Number: D20092100037), in related projects of "AI-based Ophthalmology research".

We promise that the authorized data is in accordance with China's biomedical ethics system.

Date: 18, August, 2021

知情同意书

申办者：深圳爱尔眼科医院

方案名称：眼科多模态影像处理的相关算法研究

知情同意书版本号：V2

临床试验机构：深圳爱尔眼科医院

研究者：黄丽娜、林晨、马瑛娜、王涵、李强、李青蒨

尊敬的 _____ 女士/先生，您将被邀请参加一项医学研究项目，下列各项记述了本医学研究项目背景、目的、方法、试验过程中给您带来的益处和可能产生的风险或者不便以及您的权益等，请您在参加临床试验前务必仔细阅读。本知情同意书提供给您的信息可以帮助您决定是否参加此项临床试验，如有任何疑问请向负责该项试验的研究者提问，以确保您充分理解有关的内容。您可以与家人、朋友以及您的经治大夫讨论之后再做决定。您是否参加本项试验是自愿的，如果同意参加该临床试验，请在知情同意书的声明中签字。

1. 为什么要进行这项研究？

研究项目名称：

眼科多模态影像处理的相关算法研究

研究项目目的：

人工智能辅助诊断具备很高的临床应用价值，人工智能算法结合医疗大数据的应用具备高诊断速度、高准确度、低漏诊率、低误诊率的技术特征，对医生临床诊断能力起到显著的提升作用；此外，在降低人均医疗成本和医疗资源的基层覆盖方面也起到决定性的作用。

近年来，随着人工智能技术的高速发展，人工智能技术在医疗影像领域的应用呈现遍地开花的态势。眼科在医学影像方面有数量及质量的优势，是医学与人工智能与大数据交叉融合的突破口。目前，眼底彩照检查是发现眼底疾病的最简便有效的方法，是医生完成诊断的主要依据，通过对影像的分析和比较，从而完成有依据的诊断。如能够定期进行眼底检查，可以实现对七大类的眼科疾病和三十多种慢性疾病，早发现从而进行早干预、早治疗。

眼底医生每小时阅片量约为 12(约 5min/张），人工智能每小时阅片量 1800，效率提升百倍！眼底医生漏检率较高，人工智能阅片检出率几乎为

100%。通过与影像学相结合的机器学习技术在眼科中的应用，人工智能不仅可以辅助眼科医生筛查、减轻医生的负担，更加提高临床工作中眼科疾病的诊断效率，从而极大地提高了诊疗覆盖率；通过筛查早期发现高危人群或者患病人群，提早治疗。

研究项目方法和内容：

（一）研究目的

拟利用现有成熟设备中已有的前节、后节不同模态影像，结合现有图像及数据算法，对图像特征进行提取和深入分析。寻找具有临床可行性的分析算法。评估这些算法在图像结构提取、降噪、异常结构识别、疾病分类中的应用。为进一步提高青光眼、角膜疾病、晶体和前房异常、视网膜疾病的临床诊断和分析提供图像学及算法研究基础。

（二）研究方法

多模态眼部数据的收集

前期收集和存储部分经过许可的多种模态的影像及现有设备中产生的参数数据，包括 a）OCT 数据，其中包含 CasiaOCT、Cirrus OCT、Optvue OCTA 数据，内容包括前后节图像信息、视盘黄斑血流信息及 FAZ 等参数数据、RNFL 层的相关分析数据。b）眼底数据，包括立体眼底照相机的视盘双图像数据、超广角眼底照片、海德堡造影图像，以及视盘和 RNFL 等参数的分析结果数据。c）眼前节图像：角膜地形图、眼表照片。每种照片或者数据采集约 100-3000 张。对图像质量进行评估；利用成熟算法评估现有图像及数据的可分析性。其中算法种类包括：北卡罗莱那 OCT 指数算法、FCN/UNET 结构识别算法、CycleGAN 图像降噪对比算法等。选取具有良好结构的影像类别数据建立优化算法库；同时

根据初步分析的图像结果分析采集图像过程中的问题，指导设备操作等导致的图像模糊，提高数据采集的质量。

眼部特征性解剖结构的识别任务

基于眼前节及眼底的各类相片、OCT 图像和数据，根据已知的成熟的眼部解剖学分析方法，探索基于眼底相片的眼底特征性解剖位置的识别和比对。主要分析种类有（1）前节：角膜前后边缘的线性拟合；巩膜突和房角的识别；房角参数的重新生成。 （2）晶体前后缘的参数识别及晶体厚度分析。 （3）眼底各结构：视盘各形态（包括杯盘、PPA）等特征及参数的重计算；黄斑中心区域的识别，视网膜重要异常形态（出血、渗出等）边缘识别。 根据本设备算法的结构，与人工描绘、金标准描述、原有设备描述进行结果对比，评估算法的可靠性和可重复性。

眼科疾病的识别及评价任务

基于经过上述算法处理筛选，选取具有良好表现的算法结果，必要时采集已有的可回顾性疾病资料的补充数据，与临床现有方法和结果进行对比评价，评估其诊断和预测的准确性、可重复性。拟评估的类别包括：对视盘及黄斑分析中产生的参数进行北卡罗莱那指数的分析，评估其在青光眼的诊断及预后分析效果；视盘及黄斑区的血流变化及黄斑异常的疾病类别分析；前节结构与参数在房角分类、房角和前房手术后的预后的分析；视网膜异常形态对比与视网膜疾病的分析。

主要对比的统计学方法有（1）基于 ROC 曲线的诊断准确率评估。（2）基于 ICC、Kappa 指数的可重复性评估。（3）基于时序 COX 模型的预测评估。

研究项目过程和期限：

研究期限为5年（2021.9-2026.9 ）。（1）2021.9-2023.9，完成数据收集，算法模型探索。（2）2023.9-2025.9，完成算法优化及相关纵向课题申报，发表高质量论文1。（3）2025.9-2026.9，完成系统开发，发表高质量论文1篇。

研究项目的资金来源和可能的利益冲突：无

本项研究已经得到深圳爱尔眼科医院医学伦理委员会批准。深圳爱尔眼科医院医学伦理委员会已经审议此项研究是遵从赫尔辛基宣言原则，符合医学伦理的要求。

2. 那些人适宜参加这项研究？

如果您同时存在以下任意一种情况则不宜参加本研究，因为这些情况参加研究不仅浪费您的时间，还会影响研究结果的科学性：

- 不能配合临床试验人员完成试验者
- 眼部情况不适宜参与试验者

如果您不属于上述情况，且满足以下情况，将属于适宜参加本研究：

- 能够积极配合临床试验人员完成试验者
- 眼部无明显外部创伤

您的研究医师会对您进行评估，并告诉您是否适宜参加本研究。

3. 多少人将参加这项研究？

本计划共计划招募 100 名受试者，主要在 研究/医疗机构进行。

4. 参加这项研究要做什么？

如果您入选本研究项目，入组前，您将接受以下检查以确定您是否可以参加本研究：

- 常规眼部检查

如果您以上检查合格，请按照以下步骤进行研究：

- 配合临床试验人员使用眼底相机进行超广角眼底拍摄

本研究将持续 5 分钟，无需随访及回访。

5. 参加这项研究的注意事项

当您决定参加这项研究时，需要仔细考虑上面所述的检查对您日常工作、家庭生活等可能的影响。若您对研究涉及的检查和步骤有任何疑问，可以向我们咨询。

您参加试验可能被终止的预期情况和/或原因（请列出研究的终止标准）：

- 研究中途眼部情况不适宜参与试验

参加本研究可能改善或不能改善您的健康状况，您可以选择：

✓ 不参加本研究，继续您的常规治疗。

✓ 参加别的研究。

✓ 不接受任何治疗。

请与您的医生协商您的决定。

6. 参加这项研究的可能受益

参加本研究对您没有直接益处，但我们希望从您参与的这项研究中得到的信息在将来能够使您和与您病情相同的病人获益。

7. 参加这项研究的可能的不良反应、风险和不适、不方便

本研究需要进行眼底拍摄，拍摄设备与中国大多数中高级医院对眼底诊断使用的眼底相机相同，不会带来额外的风险。

8. 参加这项研究的酬劳、费用及补偿说明

您不会因参与本研究而获得任何酬劳。本研究不增加您额外的费用。为了补偿您参加本研究可能给您带来的不便，本研究将支付您参加本研究期间所做的相关检查费用以及随访时的挂号费。

如果发生与研究有关的损害，请立即通知研究医生，他们将负责对您采取适当的治疗措施。研究团队成员将承担您的医疗费用以及按照法律法规规定给予相应的经济补偿。

即使您已经签署这份知情同意书，您仍然保留您所有的合法权利。

9. 参加这项研究的个人信息保密吗？

本研究使用您的眼底照片作为研究数据，并保留其用于将来的研究，研究团队将会采取合适的措施来保护您医疗信息资料的安全性。在研究期间，您的姓名、性别等个人可识别信息将用代号或数字代替，并予以严格的保密，只有相关的医生知道您的个人信息，您的隐私权会得到很好的保护。研究结果可能会在杂志上发表，但不会泄露您个人的任何可识别信息。

您的医疗记录（研究病历/CRF、化验单等）将完整地保存在医院，研究者、研究主管部门、伦理委员会将被允许查阅您的医疗记录。任何有关本研究结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您的个人医疗资料的隐私。

10. 必须参加这项研究吗？

参加本研究是完全自愿的，您可以选择不参加本项研究项目，或者研究过程中的任何时候选择退出研究，不需要任何理由。这个决定不会影响您未来的治疗。

如果您决定退出本研究，请提前通知您的研究医生。为了保障您的安全，您可能被要求进行相关检查，这对保护您的健康是有利的。

11.怎样获得更多的信息？

您可随时了解与本项目有关的信息资料和研究进展，如果您有与本项目有关的问题，或您在项目过程中发生了任何不适与损伤，或有关于本项目参加者权益方面的问题您可以通过 19116987045 与王涵联系。

深圳爱尔眼科医院医学伦理委员会咨询电话：0755-83970888-8031/8600

邮箱：sz0755lunli@163.com

地址：广东省深圳市福田区华强南路 2048 号

受试者同意声明

我已经仔细阅读了本知情同意书，我有机会提问而且所有问题均已得到解答。我理解参加本项试验是自愿的，我可以选择不参加本项目，或者在任何时候通知研究者后退出而不会遭到歧视或报复，我的任何医疗待遇与权益不会因此而受到影响。

如果我需要其他诊断/治疗，或者我没有遵守试验计划，或者有其他合理原因，研究者可以终止我继续参与本项目。

我自愿同意参加该项目，我将收到一份签过字的“知情同意书”副本。

受试者签名： 日期： 年 月 日

联系电话：

受试者因无行为能力等原因不能签署知情同意的，或受试者为未成年人的，由其监护人签署。

监护人签名： 日期： 年 月 日

同受试者关系： 联系电话：

受试者不能签署知情同意书的理由：

研究者声明

我已准确地将知情同意书内容告知受试者并对受试者的提问进行了解答，受试者自愿参加本项目。

研究者签名： 日期： 年 月 日

联系电话：19116987045

Informed consent form

Sponsor: Shenzhen Aier Eye Hospital

Scheme Name: Research on Related Algorithms of Ophthalmic Multimodal Image Processing

Informed Consent Version No.: V2

Clinical trial institution: Shenzhen Aier Eye Hospital

Researchers: Lina Huang, Chen Lin, Yingna Ma, Han Wang, Qiang Li, Qingzhi Li

Dear Ms./Mr. The information provided in this PIC form will help you decide whether to participate in this clinical trial. If you have any questions, please ask the researcher in charge of the trial to ensure that you fully understand the relevant contents. You can discuss with your family, friends and your doctor before making a decision. Whether you participate in this trial is voluntary. If you agree to participate in this clinical trial, please sign the statement of informed consent.

1. Why do you want to do this research?

Name of research project:

Research on Related Algorithms of Ophthalmic Multimodal Image Processing

Objectives of the research project:

Artificial intelligence-assisted diagnosis has high clinical application value. The application of artificial intelligence algorithm combined with medical big data has the technical characteristics of high diagnosis speed, high accuracy, low missed diagnosis rate and low misdiagnosis rate, which plays a significant role in improving doctors' clinical diagnosis ability; In addition, it also plays a decisive role in reducing the per capita medical cost and the grass-roots coverage of medical resources.

In recent years, with the rapid development of artificial intelligence technology, the application of artificial intelligence technology in the field of medical imaging has blossomed everywhere. Ophthalmology has the advantages of quantity and quality in

medical imaging, which is a breakthrough in the cross-integration of medicine, artificial intelligence and big data. At present, fundus color examination is the most convenient and effective method to find fundus diseases, and it is the main basis for doctors to complete diagnosis. Through the analysis and comparison of images, the diagnosis can be completed. If fundus examination can be carried out regularly, seven categories of ophthalmic diseases and more than 30 kinds of chronic diseases can be detected early, so as to carry out early intervention and early treatment.

Fundus doctors read about 12 films per hour (about 5min/sheet), and artificial intelligence reads 1800 films per hour, which improves the efficiency by 100 times! The missed detection rate of fundus doctors is high, and the detection rate of artificial intelligence reading films is almost 100%. Through the application of machine learning technology combined with imaging in ophthalmology, artificial intelligence can not only assist ophthalmologists in screening, reduce the burden on doctors, but also improve the diagnosis efficiency of ophthalmic diseases in clinical work, thus greatly improving the coverage rate of diagnosis and treatment; Early detection of high-risk groups or sick groups through screening and early treatment.

Method and content of research project:

(a) the purpose of the research

It is proposed to extract and deeply analyze the image features by using the existing different modal images of the front section and the back section in the existing mature equipment, combined with the existing image and data algorithms. Looking for a clinically feasible analysis algorithm. Evaluate the application of these algorithms in image structure extraction, noise reduction, abnormal structure

recognition and disease classification. To further improve the clinical diagnosis and analysis of glaucoma, corneal diseases, lens and anterior chamber abnormalities, retinal diseases to provide imaging and algorithm research basis.

(2) Research methods

Collection of multimodal eye data

Collect and store partial licensed multi-modal images and parameter data generated in existing equipment in the early stage, including a) OCT data, including CasiaOCT, Cirrus OCT, Optvue OCTA data, including anterior and posterior segment image information, macular blood flow information of optic disc, FAZ and other parameter data, and related analysis data of RNFL layer. B) Fundus data, including optic disc dual image data of stereo fundus camera, ultra-wide angle fundus photos, Heidelberg angiography images, and analysis result data of optic disc and RNFL parameters. C) Images of the anterior segment: Corneal topography, ocular surface photographs. About 100-3000 photos or data are collected for each type. Evaluate the image quality; Using mature algorithms to evaluate the analyzability of existing images and data. The algorithms include: North Carolina OCT index algorithm, FCN/UNET structure recognition algorithm, CycleGAN image denoising contrast algorithm and so on. Select image category data with good structure to establish an optimization algorithm library; At the same time, according to the preliminary analysis of the image results, the problems in the process of image acquisition are analyzed, which can guide the image blurring caused by equipment operation and improve the quality of data acquisition.

Recognition task of eye characteristic anatomical structure

Based on all kinds of anterior segment and fundus photos, OCT images and data, according to the known mature eye anatomical analysis methods, this paper explores the recognition and comparison of fundus characteristic anatomical positions based on fundus photos. The main analysis types are (1) anterior segment: linear fitting of anterior and posterior corneal edges; Identification of scleral process and anterior chamber angle; Regeneration of chamber angle parameters. (2) Parameter identification of front and rear edges of crystal and analysis of crystal thickness. (3) Fundus structures: recalculate the characteristics and parameters of optic disc shapes (including cup and disc, PPA); Recognition of the central area of macula and edge recognition of important abnormal forms of retina (hemorrhage, exudation, etc.). According to the structure of this device algorithm, the results are compared with manual description, gold standard description and original device description to evaluate the reliability and repeatability of the algorithm.

Identification and Evaluation of Ophthalmic Diseases

Based on the above algorithm processing and screening, select the algorithm results with good performance, collect the supplementary data of existing retrospective disease data when necessary, and compare and evaluate with the existing clinical methods and results to evaluate the accuracy and repeatability of diagnosis and prediction. The categories to be evaluated include: North Carolina Index analysis of parameters generated in optic disc and macular analysis to evaluate its diagnostic and prognostic effects in glaucoma; Changes of blood flow in optic disc and macular area and analysis of disease categories of macular abnormality; Analysis of anterior segment structure and parameters in angle classification, angle and prognosis after

anterior chamber surgery; Comparison of abnormal retinal morphology and analysis of retinal diseases.

The main comparative statistical methods are: (1) Evaluation of diagnostic accuracy based on ROC curve. (2) Repeatability evaluation based on ICC and Kappa index. (3) Prediction and evaluation based on time series COX model.

Process and duration of research project:

The research period is 5 years (September 2021.9-September 2026.9). (1) From September 2021 to September 2023, complete data collection and algorithm model exploration. (2) 2023.9-2025.9, complete algorithm optimization and related longitudinal subject declaration, and publish high-quality papers 1. (3) From September 2025.9 to September 2026.9, the system was developed and one high-quality paper was published.

Funding sources and possible conflicts of interest of research projects: None

This study has been approved by the Medical Ethics Committee of Shenzhen Aier Eye Hospital. The Medical Ethics Committee of Shenzhen Aier Eye Hospital has considered that this study complies with the principles of Helsinki Declaration and meets the requirements of medical ethics.

2. Who are the right people to take part in the study?

If you have any of the following conditions, you should not participate in this study, because participating in the study will not only waste your time, but also affect the scientific nature of the research results:

- Unable to cooperate with clinical trial personnel to complete the trial

- The eye condition is not suitable for participants

If you do not belong to the above conditions and meet the following conditions, you will be suitable to participate in this study:

- Those who can actively cooperate with clinical trial personnel to complete the trial
- There is no obvious external trauma to the eye

Your research physician will evaluate you and tell you whether you are suitable for this study.

3. How many people will take part in the study?

A total of 100 subjects are planned to be recruited in this program, mainly in research/medical institutions.

4. What should I do to participate in this research?

If you are selected for this study, you will undergo the following tests to determine whether you can participate in this study before joining the group:

- Routine eye examination

If you pass the above inspection, please follow the following steps to study:

- Cooperate with clinical trial personnel to use fundus camera for ultra-wide-angle fundus shooting

This study will last for 5 minutes without follow-up and return visit.

5. Considerations for participating in this study

When you decide to participate in this study, you need to carefully consider the possible impact of the above examination on your daily work, family life and so on. If you have any questions about the inspection and procedures involved in the research, you can consult us.

The expected circumstances and/or reasons for which your participation in the trial may be terminated (please list the termination criteria of the study):

- The eye condition in the middle of the study is not suitable for participating in the experiment

Participating in this study may or may not improve your health. You can choose:

✓ Do not participate in this study and continue your routine treatment.

✓ Participate in other studies.

✓ Don't receive any treatment.

Please consult your doctor about your decision.

6. Possible benefits of participating in this study

There is no direct benefit to you from participating in this study, but we hope that the information you get from participating in this study will benefit you and patients with the same condition in the future.

7. Possible adverse reactions, risks and discomfort and inconvenience of participating in this study

This study requires fundus photography, which is the same as the fundus cameras used in most middle and senior hospitals in China, and will not bring additional risks.

8. Statement of remuneration, fees and compensation for participation in the study

You will not receive any reward for participating in this study. This study does not increase your extra cost. In order to compensate for the inconvenience caused by your participation in this study, this study will pay the relevant examination fees during your participation in this study and the registration fee during the follow-up.

If research-related damage occurs, please inform the research physician immediately, who will be responsible for taking appropriate treatment measures for you. The members of the research team will bear your medical expenses and give corresponding financial compensation according to laws and regulations.

Even if you have signed this informed consent form, you still reserve all your legal rights.

9. Is the personal information involved in this study confidential?

In this study, your fundus photos are used as research data, and they are reserved for future research. The research team will take appropriate measures to protect the security of your medical information. During the study, your name, gender and other personally identifiable information will be replaced by codes or numbers, and will be kept strictly confidential. Only the relevant doctors know your personal information, and your privacy rights will be well protected. The results of the study may be published in a journal, but will not reveal any personally identifiable information about you.

Your medical records (research medical records/CRF, test sheets, etc.) will be kept intact in the hospital, and researchers, research authorities and ethics committees

will be allowed to access your medical records. Any public report on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the scope permitted by law.

10. Do you have to participate in this study?

Participation in this study is completely voluntary. You can choose not to participate in this research project, or choose to quit the study at any time during the research process, without any reason. This decision will not affect your future treatment.

If you decide to quit this study, please inform your research doctor in advance. In order to protect your safety, you may be required to carry out relevant examinations, which is beneficial to protect your health.

11. How to get more information?

You can keep abreast of the information and research progress related to this project. If you have any problems related to this project, or if you have any discomfort or injury during the project, or if you have any problems related to the rights and interests of participants in this project, you can contact Wang Han through 19116987045.

Medical Ethics Committee of Shenzhen Aier Eye Hospital Tel: 0755-83970888-8031/8600

Email: sz0755lunli@163.com

Address: No.2048 Huaqiang South Road, Futian District, Shenzhen City, Guangdong Province

Subject consent statement

I have read this PIC carefully, I have had the opportunity to ask questions and all questions have been answered. I understand that my participation in this trial is voluntary, and I can choose not to participate in this project, or quit after notifying the researchers at any time without discrimination or retaliation, so that my medical treatment and rights will not be affected.

If I need other diagnosis/treatment, or I do not follow the trial plan, or for other reasonable reasons, the researcher may terminate my participation in this project.

I voluntarily agree to participate in this project, and I will receive a signed copy of the Informed Consent Form.

Subject signature: Date: Year, month and day

Contact number:

If the subject is unable to sign informed consent due to incapacity and other reasons, or if the subject is a minor, it shall be signed by his guardian.

Signature of Guardian: Date: Year, month and day

Relationship with subjects: Contact telephone number:

Reasons why subjects cannot sign informed consent:

Researcher's statement

I have accurately informed the subjects of the contents of the informed consent form and answered their questions, and the subjects volunteered to participate in this project.

Signature of researcher: date: year, month and day

Tel: 19116987045