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）
免除知情同意书（版本号: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>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
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）
年 月 日</td></tr>
</table>

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 Waiver of 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)

免除知情同意申请表

项目名称	眼科图像处理相关算法研究项目
请参照并对应以下条目，说明该研究拟申请免除知情同意的理由： 如不满足以下条目相关要求，则无法申请免除知情同意。请在申请材料中准备知情同意书	
□1.利用以往临床诊疗中获得的数据/生物标本的研究，申请免除知情同意	
本研究使用的数据或生物标本是以往临床诊疗中获取的。本研究不利用患者以前已明确地拒绝利用的医疗记录和标本 请说明：本项目采用的数据无患者明确拒绝利用的理疗记录及样本。	
本研究对受试者的风险不大于最小风险（指研究中预期风险的可能性和程度不大于日常生活、或进行常规体格检查或心理测试的风险）。 请说明：本研究实现对受试者眼部照片数据采集，不涉及对受试者眼部任何损伤行为。	
免除知情同意不会对受试者的权利和健康产生不利的影响。 请说明：免除知情同意不会侵犯任何受试者的权力和健康，采集数据存储均为脱敏信息，已经无法找到该受试者，体现受试者个人信息，且研究项目不涉及个人隐私和商业利益的。	
受试者的隐私和个人身份信息得到保护。 请说明：采集数据存储均为脱敏信息，不体现受试者个人信息，保护受试者隐私和个人信息，已经无法找到该受试者，研究项目不涉及个人隐私和商业利益的。	
若规定需获取知情同意，研究将无法进行（病人有权知道其病历/标本可能用于研究，其拒绝或不同意参加研究，不是研究无法实施、免除知情同意的证据）。 请说明：回顾性研究涉及到的过往数据已经无法找到该受试者。	
本研究不需要进一步随访获取受试者信息。	
本研究利用可识别身份信息的生物样本或者数据进行研究，已无法找到该受试者，且研究项目不涉及个人隐私和商业利益。	
2. 研究中获得信息/生物标本的二次利用，申请免除知情同意	
以往研究已获得受试者的书面同意，允许其他的研究项目使用其信息或标本。 请说明：研究中对于 45° 眼底相片，在其他相关研究中有部分数据公开可以作为对照数据进行使用。	
本次研究符合原知情同意的许可条件。 请说明：本研究不涉及对于原研究数据的任何不恰当行为，符合知情同意许可条件。	
受试者的隐私和身份信息的保密得到保证。 请说明：获取的数据均为脱敏数据。	
本研究对受试者的风险不大于最小风险 请说明：本研究对于受试者不存在身心潜在侵害，无风险，研究项目不涉及个人隐私和商业利益的。	
研究者签名：黄丽娜 申请日期：2021.11.8	

Application for Exemption from Informed Consent

Project name	Research Project of Ophthalmic Image Processing Related Algorithms

Please refer to and correspond to the following entries to explain the reasons why the study intends to apply for exemption from informed consent:
If the relevant requirements of the following items are not met, you cannot apply for exemption from informed consent. Please prepare the informed consent form in the application materials

1. Use the data obtained from previous clinical diagnosis and treatment/biological specimen research to apply for exemption from informed consent

The data or biological specimens used in this study were obtained from previous clinical diagnosis and treatment. This study does not use medical records and specimens that patients have explicitly refused to use before
Please explain: The data used in this project have no physiotherapy records and samples that patients explicitly refuse to use.

The risk of this study to the subjects is not greater than the minimum risk (that is, the possibility and degree of the expected risk in the study are not greater than the risk of daily life or routine physical examination or psychological test).
Please explain: This study realizes the collection of eye photo data of the subjects, and does not involve any eye injury behavior of the subjects.

Exemption from informed consent will not have adverse effects on the rights and health of subjects.
Please explain: Exemption from informed consent will not infringe on the rights and health of any subject, the collected data are desensitized information, the subject can no longer be found, reflecting the personal information of the subject, and the research project does not involve personal privacy and commercial interests.

The privacy and personal identity information of the subjects are protected.

Please explain: The collected data storage is desensitized information, which does not reflect the personal information of the subject, protects the privacy and personal information of the subject, and can no longer find the subject. The research project does not involve personal privacy and commercial interests.

If informed consent is required, the study will not be carried out (patients have the right to know that their medical records/specimens may be used for the study, and their refusal or disagreement to participate in the study is not evidence that the study cannot be carried out and informed consent is exempted).

Please explain: The past data involved in the retrospective study can no longer find the subject.

This study does not need further follow-up to obtain subject information.

In this study, biological samples or data that can identify identity information are used for research, but the subject can no longer be found, and the research project does not involve personal privacy and commercial interests.

2. Reuse of information/biological specimens obtained in research, and application for exemption from informed consent

Previous studies have obtained the written consent of the subjects, allowing other research projects to use their information or specimens.
Please explain: For 45 fundus photos in the study, some data are published in other related studies and can be used as control data.

This study meets the licensing conditions of the original informed consent.
Please state that this study does not involve any inappropriate behavior with the original study data, and meets the licensing conditions of informed consent.

The privacy of subjects and the confidentiality of identity information are guaranteed.
Please explain: All the data obtained are desensitized data.

The risk of this study to the subjects is not greater than the minimum risk
Please explain: There is no potential physical and mental harm, no risk, and the research project does not involve personal privacy and commercial interests.

Signature of researcher: Lina Huang

Date of application: 2021.11.8

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