重庆大学肿瘤医院伦理委员会

编码：CZLS2023351-A **日期： 2023.12.15**

项目名称	血清糖抗原 19-9 与肿瘤缩小率在胰腺导管癌的联合预后价值		
申请单位	肿瘤医院		
科室	综合治疗中心	研究者	夏冬琴

检查报告：

伦理委员会成员通过快速审查仔细审查了提交的研究方案、研究人员资格和知情同意书，认为提交的材料基本符合伦理要求。评审结果：同意。

EC 严格按照 GCP 和相关规定的要求进行建设、运营和实施。

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注：

1.充分尊重主体的尊严和自主权，确保主体在充分理解的情况下自愿作出决定。

2.再培训局会继续检讨这项研究。无论研究是否启动，请根据 EC 规定的跟踪频率，在正在进行的审查到期日前至少 1 个月及时提交正在进行的评审报告。

3.批准的研究应根据 IRC 批准的计划以及相关法律法规和《赫尔辛基宣言》的原则进行。

4.如果临床研究提前暂停/终止，请及时向伦理委员会报告。

5.死亡的严重不良事件以及可疑和意外的严重不良反应必须及时向再培训局报告。

6.对实验方案的任何修改、知情同意书和其他材料批准

Ethical Review Statement of the

Chongqing University Cancer Hospital

Ethical code: CZLS2023351-A **Review date: 15 Dec 2023**

Project name	Combining Prognostic Value of Serum CA 19-9 and Tumor Size Reduction Ratio in Patients with Pancreatic Ductal Adenocarcinoma Underwent Neoadjuvant Therapy		
Applicant	Chongqing University Cancer Hospital		
Department/Institute	Oncology Treatment Center of Traditional Chinese Medicine	Principal Investigator	Dongqin Xia

Examination report:

Members of the Ethics Committee carefully reviewed the submitted research protocol 、researchers' qualifications and informed consent form through rapid review, and believed that the submitted materials basically met the ethical requirements..Review Result: Agreed.

The EC is constructed, operated and implemented in strict accordance with the requirements of the GCP and relevant regulations.

Affiliated Chongqing University Cancer Hospital Ethics Committee (Seal)

Date: 15 Dec 2023

Note:

1. Fully respect the dignity and autonomy of the subject, and ensure that the subject makes a consensual decision voluntarily under the condition of full understanding.
2. The study will be subject to ongoing review by the ERB. No matter whether the study is initiated or not, please timely submit the ongoing review report at least 1 month before the expiration date of the ongoing review according to the tracking frequency specified by the EC.
3. The approved studies shall be carried out in accordance with the program approved by the IRC and in accordance with the relevant laws and regulations and the principles of the Helsinki Declaration.
4. If the clinical study is suspended/terminated early, please report to the Ethics Committee in time.
5. Serious adverse events of death and suspicious and unexpected serious adverse reactions must be reported to the ERB in a timely manner.
6. Any modification of the experimental scheme, informed consent and other materials approved by the Ethics Committee, as well as the replacement of the main investigator, shall be timely notified to the Ethics Committee for re-examination, and shall be implemented upon approval.

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