

# 免除知情同意申请书

尊敬的伦理委员：

我是昆明医科大学第二附属医院肝胆胰外科二病区的邹浩，我们团队拟于2023年4月-2023年10月开展胆囊管解剖变异与胆囊结石的预测模型的构建与验证的研究。该研究为回顾性病例对照研究，需要收集来自我院病案科2021年10月至2022年1月诊断为胆囊结石患者的病例资料以及同期诊断为肝血管瘤、胰腺肿瘤、肝癌的患者病例资料。根据我院的《临床研究伦理审查申请/报告指南》，我们的研究满足以下相关的规定：“利用以往临床诊疗中获得的医疗记录和生物标本的研究，并且符合以下全部条件：1.研究目的是重要的。2.研究对受试者的风险不大于最小风险。3.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。4.受试者的隐私和个人身份信息得到保护。”因此，我们申请免除知情同意。

申请人：邹浩

2023年04月03日

## **Application for Exemption from Informed Consent**

Dear Ethics Committee:

I am Hao Zou from the Department of Hepatobiliary Pancreatic Surgery of the Second Affiliated Hospital of Kunming Medical University. Our team proposes to conduct a study on the construction and validation of a predictive model of gallbladder duct anatomical variation and gallbladder stones from April 2023 to October 2023. The study is a retrospective case-control study and requires the collection of data from patients diagnosed with gallbladder stones from October 2021 to January 2022 and patients diagnosed with hepatic hemangioma, pancreatic tumour and hepatocellular carcinoma in the same period. According to our Clinical Research Ethics Review Application/Reporting Guidelines, our study meets the following relevant regulations: "Research that utilizes medical records and biological specimens obtained from previous clinical visits and meets all of the following conditions: 1. The purpose of the research is significant. 2. The risk to the subject of the research is no greater than minimal. 3. The waiver of informed consent will not have an impact on the subject's privacy and personally identifiable information is protected." Therefore, we request a waiver of informed consent.

Applicant: Hao Zou  
Date: 04/03/2023