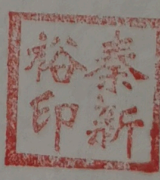



# 伦理委员会批准函

## Ethics Committee Approval Letter

审查编号 Approval No.: B2020-206R

项目名称 Study Title	不同气腹压力对于腹腔镜下肝脏肿瘤切除术中气栓风险影响的随机、对照临床研究		
试验产品名称 Study Product Name	NA	产品类别/规格 Product Category	NA
批准文号及发文单位(Approval No. and Issued By) NA	研究分期(Phase of Study) NA		
主要研究者(Principal Investigator) 钟静	申办者(Sponsor) 复旦大学附属中山医院		
审查方式及日期 (Type & Date of Review)	<input checked="" type="checkbox"/> 会议审查 (Meeting Review) <u>2020年08月20日</u> <input checked="" type="checkbox"/> 快速审查(Expedited Review) <u>2020年08月21日</u>		
会议地点 (Meeting Location)	复旦大学附属中山医院 5 号楼 211 会议室		
会议出席情况 (Meeting Attendance)	出席(Attendance) <u>10</u> 人, 投票(Vote) <u>10</u> 人, 回避(Avoidance) <u>0</u> 人		
下列研究相关文件已经批准 The following documents have been approved			
1. 研究方案: v2.0 2020.08.20 2. 知情同意书: v2.0 2020.08.20 3. 研究者简历 4. 研究人员名单 5. 病例报告表: v1.0, 2020.08.08			
审查决定 Decision for this proposal and have been [ <input checked="" type="checkbox"/> ]: <input checked="" type="checkbox"/> 同意 Approval			
持续审查频率: <input type="checkbox"/> 3 个月/3 Months <input type="checkbox"/> 6 个月/6 Months <input checked="" type="checkbox"/> 1 年/1Year <input type="checkbox"/> 不适用/NA 批准函有效期至: 2021 年 08 月 21 日			
主任委员/副主任委员签名 Chair/Vice Chair Signature:		 	
批准日期 Approval Date:		2020.8.21	
复旦大学附属中山医院伦理委员会(盖章)Stamp of ZSEC			



**Ethics Committee Approval Letter**

**Approval NO: B2020-206R**

<b>Study Title</b>	Gas embolism under standard versus low pneumoperitoneum pressure during laparoscopic liver resection (GASES): a randomized, controlled trial		
<b>Study Product Name</b>	NA	<b>Product Category</b>	NA
<b>Approval NO. and Issued By:</b> NA		<b>Phase of Study:</b> NA	
<b>Principal Investigator</b> Jing Zhong		<b>Sponsor</b> Zhongshan Hospital Fudan University	
<b>Type &amp; Date of Review</b>	<input checked="" type="checkbox"/> <b>Meeting Review:</b> 20-08-2020 <input checked="" type="checkbox"/> <b>Expedited Review:</b> 21-08-20		
<b>Meeting Location</b>	No.211 Meeting Room, Building 5, Zhongshan Hospital Fudan University		
<b>Meeting Attendance</b>	Attendance: 10 Persons Vote: 10 Persons Avoidance: 0 Person		
The following documents have been approved: <ol style="list-style-type: none"> <li>1. Study design: version 2.0 of 20-08-2020</li> <li>2. Informed consent: version 2.0 of 20-08-2020</li> <li>3. Principal investigator profile</li> <li>4. The list of investigators</li> <li>5. Case report form: version1.0 of 08-08-2020</li> </ol>			
Decision for this proposal and have been [ <input checked="" type="checkbox"/> ]: <input checked="" type="checkbox"/> Approval Frequency of continuous review: <input type="checkbox"/> 3Months <input type="checkbox"/> 6Months <input checked="" type="checkbox"/> 1 Year <input type="checkbox"/> NA Expiration of approval letter: 21-08-2021 Chair/Vice Chair Signature: Xinyu Qin Approval Date: 21-08-2020 Stamp of ZSEC:			

A-024 Version:3.4