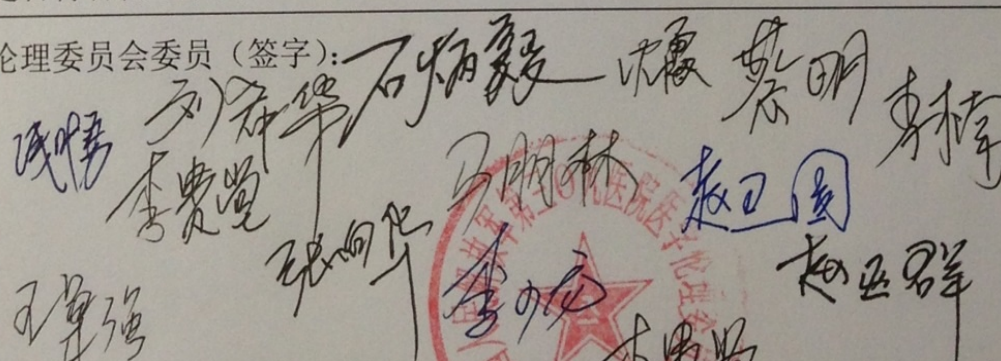


# 军队医疗机构临床试验申请及伦理委员会审查表

研究项目基本情况	项目名称	肝脏移植术后脾动脉盗血综合征的预防和治疗		
	申请科室	器官移植中心	项目负责人	杜国盛
	研究疾病	肝脏移植术后脾动脉盗血综合征	研究设计	非随机对照研究
	研究类别	预防性研究	研究阶段	I 期临床试验
	经费来源	自筹	起止时间	2005.01—2009.12
	研究目的	探索肝移植术后脾动脉盗血综合征的预防策略,同时寻找治疗脾动脉盗血综合征的合理治疗措施。		
	简要研究方法	脾动脉增粗是脾动脉盗血综合征的高危因素,通过肝移植术中缩扎脾动脉根部,达到减少脾动脉血流的目的,保证肝动脉血供,进而预防脾动脉盗血综合征。同时采取 DSA 下脾动脉栓塞等措施对脾动脉盗血患者进行治疗。		
	成果表达形式	论文	成果应用范围	军民两用
研究项目是否符合国家各项法律、法规			<input checked="" type="checkbox"/> 是	<input type="checkbox"/> 否
研究项目是否符合《赫尔辛基宣言》			<input checked="" type="checkbox"/> 是	<input type="checkbox"/> 否
研究项目是否征得患者同意并签署知情同意书			<input checked="" type="checkbox"/> 是	<input type="checkbox"/> 否
研究项目是否已充分论证试验可行性			<input checked="" type="checkbox"/> 是	<input type="checkbox"/> 否
研究项目是否已排除对患者造成严重副反应可能性			<input checked="" type="checkbox"/> 是	<input type="checkbox"/> 否
伦理委员会审查时间: 2004.11.12		审查地点: 器官移植中心		记录人: 叶楠
伦理委员会应到人数: 13		实到人数: 13		回避人数: 0
讨 论 意 见	是否符合医学和伦理原则(可附页) 符合医学和伦理原则 记录人签名: 叶楠 2004 年 11 月 12 日			
表决结果	同意: 13 票; 暂缓: 0 票; 不同意: 0 票; 弃权: 0 票;			
伦理委员会意见	是否符合伦理准则: <input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否; 是否同意实施该研究项目: <input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否			
	伦理委员会委员(签字):  伦理委员会领导(盖章): 李贵堂 2004 年 11 月 12 日			

### Ethics committee for Clinical trial application of PLA medical institutions(translation)

	Title	Prevention and Treatment to Splenic Artery Steal Syndrome after Liver Transplantation		
	Department	Organ Transplant Center	Authour	Guo-Sheng Du
	Disease	Splenic Artery Steal Syndrome	Design	Non-randomised
	Category	Preventability	Phase	Phase I Trial
	Fund	Self-finance	Time	2005.01-2009.12
	Purpose	To explore a prophylactic procedure to reduce the incidence of SASS.		
	Methods	We will select patients whose diameter of the splenic artery exceeds 5mm and/or 1.5 times of the diameter of the hepatic artery as subjects. Banding the splenic artery will be performed in some patients during the OLT. The complications in these patients will be compared with the complications in patients whose hepatic arteries aren't narrowed.		
Prospective achievement	Papers	Application of Results	Military and Civilian	
Does the research conform to all state laws			√Yes	<input type="checkbox"/> No
Does the research conform to Declaration of Helsinki			√Yes	<input type="checkbox"/> No
Whether patient consent and signed informed consent			√Yes	<input type="checkbox"/> No
Whether the research has been demonstrate feasibility fully test			√Yes	<input type="checkbox"/> No
Whether the research has ruled out the patients with severe side effects			√Yes	<input type="checkbox"/> No
Review time: Nov 12th, 2004		Review local: Organ Transp Center	Recorder: Nan Ye	
Should above number of people: 13		Real number: 13	Avoid people: 0	
Discussion Comment	<p><b>If accord with Ethics Criterion:</b> This study was according with the Ethical Committee for Human Research of the 309th Hospital of Chinese PLA</p> <p style="text-align: right;"><b>Recorder: Nan Ye</b>    Nov 12th, 2004</p>			
Results	Agree: 13;    Postpone: 0;    Oppose:0;    Abstention:0.			
Ethics Committee Comment	<p><b>If accord with Ethics Criterion:</b>√Yes <input type="checkbox"/> No; <b>If approve the research:</b> √Yes <input type="checkbox"/> No.</p>			
	<p><b>Ethics committee Member (Signature):</b> Xi-Hua Liu, Gui-Tang Li, Bingyi Shi, Nan Li, Ming Cai, Ye-Yong Qian, Zhuo-Qiang Wang, Peng-Lin Ma, Wei-Guo Zhao, Xiang-Hua Zhang, Ya-Qun Zhao, Xiao-Long Li, Xia Shen</p> <p style="text-align: right;"><b>Ethics committee leader:</b> Gui-Tang Li    Nov 12th, 2004</p>			



# 军队医疗机构活体器官移植申报审批表

活体器官捐献人	姓名	██████	性别	女	年龄	32	血型	O
	身份证号	152701198010120926					捐献器官	肝脏
	常住地址	北京市房山区韩村河镇大自然雅苑 13-4-302						
	传染病检查: 甲肝、丙肝、丁肝、戊肝、艾滋病、梅毒均阴性, 乙肝表面抗体阳性。							
活体器官接受人	姓名	██████	性别	男	年龄	39	血型	A
	身份证号	412825197302189138					接受器官	肝脏
	常住地址	北京市房山区韩村河镇大自然雅苑 13-4-302						
活体器官捐献人与接受人关联情况	活体器官捐献人自愿无偿捐献器官和接受人同意接受捐献器官的书面意愿 (√, 否)							
	2、活体器官捐献人满 18 周岁且具有完全民事行为能力 (√, 否)							
	3、活体器官捐献人与接受人关系: <u>夫妻</u> , 存在配偶、直系血亲或者三代以内旁系血亲证明材料 (√, 无)							
	4、评估摘取器官可能对活体器官捐献人健康产生的影响, 确认不会因捐献活体器官而损害捐献者正常的生理功能, 签署知情同意书 (√, 否)							
科室意见	1、活体器官捐献人和接受人提供的材料是否齐全、真实、合法 (√, 否)							
	2、活体器官捐献人和接受人其关系是否符合要求 (√, 否)							
	3、器官的配型和接受人的适应症是否符合人体器官移植技术规范 (√, 否)							
伦理委员会		经治医师签名: <u>李强</u> 科主任签名: <u>王强</u> 2012年 9 月 20 日 1、活体器官捐献人和接受人关系是否合法 (√, 否) 2、器官的配型和接受人的适应症是否符合人体器官移植技术规范 (√, 否) 3、确认不会因捐献活体器官而损害捐献者正常生理功能的评估全面、科学 (√, 否)						
伦理委员会领导签名:		<u>王强</u> 2012年 9 月 28 日						
手术室再次确认身份	活体器官捐献人与接受人接入手术室, 由临床科室医师和手术室工作人员再次确认身份, 并照相留影。 麻醉医师 (签字): <u>李强</u> 手术室护士长 (签字): <u>王强</u> 年 月 日							
医疗机构审查意见	医疗机构 (盖章):  医院领导 (签字): <u>王强</u> 2012年 9 月 28 日 此证以加此证为本医疗机构合法有效, 并须加盖出具人单位公章及编号。							
军区级单位卫生行政部门审批意见	卫生主管部门 (盖章): <u>同意</u> 2012 年 10 月 10 日 卫生局							

**Sample of living donor liver transplantation approval of PLA medical institutions(translation)**

Living donor	Name		Sex	Female	Age	32	Blood type	O
	ID						Donated organ	Liver
	Address	13-4-302 DazirranYayuan, HanCunHe, FangShan, Beijing						
	Examination: positive finding: HBV; negative findings: HAV, HCV, HDV, HEV, HIV, Syphilis							
Recipient	Name		Sex	Male	Age	39	Blood type	A
	ID						receptive organ	Liver
	Address	13-4-302 DazirranYayuan, HanCunHe, FangShan, Beijing						
Relationship between donor and recipient	Is it unbidden that the donor donates the organ?							√Yes No
	Is the donor over 18-year old and independent?							√Yes No
	Relationship between donor and recipient: couple Are the relationship certifications sufficient?							√Yes No
	Whether the operation has ruled out the donor with severe side effects?							√Yes No
	Are the referred certifications sufficient, real and legalized?							√Yes No
	Is the relationship between donor and recipient permitted?							√Yes No
	Are the match and the indication of recipient to accord with the administer standard of human organ transplantation?							√Yes No
	Doctor: Ji-Yong Song                      chief of the department: Guo-Sheng Du      Sep. 20 <sup>th</sup> , 2012							
	Is the relationship between donor and recipient legalized?							√Yes No
	Are the match and the indication of recipient to accord with the administer standard of human organ transplantation?							√Yes No
	Is the evaluation about the side effects to the donor discreet?							√Yes No
	Leader of Ethics Committee: Tian-Jun Gao    Sep. 28 <sup>th</sup> , 2012							
Anesthetist's repeat confirm	The surgeon, anesthetist and nurse ensure the identity of the donor and the recipient at the same time when they were moved to the operation toom.  Anesthetist: Heng-Lin Wang, Ji-Jie Li                      Nurse leader: Ming-Lan Shi							
Approval of medical institution	Agree!      Enhance the treatment of the complications after the operation.  Signet of medical institution    Leader of the hospital: Tian-Jun Gao Sep. 28 <sup>th</sup> , 2012							
Approval of higher department	Agree!  Signet of competent department    Oct. 10 <sup>th</sup> , 2012							