

**Examination and approval of clinical medicine by Medical Ethics Committee of
Peking University People's Hospital**

[2013] NO. (09)

Review project name	Acupuncture balanced anesthesia used in abdominal operation and its protective effects			
Application Department	Department of Anesthesiology	Project Leader: Yi Feng		Title: Professor
		Main participant: Qi Yan		Title: Resident
		Head of Department: Yi Feng		Title: Professor
Funding: 973 project				
Declaration document	1. Application Form for Ethical Review 2. Research Programmes 3. Informed Consent Form (Version 1.0)		Participating units	Five Units, including Peking University Third Hospital
Meeting time: 14 May 2013		Meeting Venue: Conference Room 15, Peking University People's Hospital		
Comments of the Ethics Committee	Agree	Consent after necessary modification	Disagree	Revision and retrial
		√		
	To amend the Informed Consent Form: 1. Unify the name of "operation item"; 2. Detailed introduction of "operation steps"; 3. Explain "randomness" and suggest optimizing "group name". 4. Inform the blood sampling test items in detail; 5. Individual "About Fees" and clearly inform free items; 6. Supplementary adverse reactions and treatment measures of the tested products; 7. To supplement this test, it is necessary to follow the Regulations on Clinical Trials of Medical Devices. 8. Correct text errors. Signature by the Chairman (Vice-Chairman): Date:			

北京大学人民医院医学伦理委员会临床医学审评批件

[2013] 院伦审临医字第 (09) 号

评审项目名称	针药复合麻醉在腹部手术的应用及机体保护效应			
申请科室	麻醉科	项目负责人: 冯 艺	职 称: 教 授	
		主要参加者: 闫 捷	职 称: 住院医师	
		科室负责人: 冯 艺	职 称: 教 授	
课题来源: 973				
申报文件	1. 伦理审查申请表 2. 研究方案 3. 知情同意书 (Version 1.0)		参 加 单 位	北京大学第三医院等 5 家单位
会议时间: 2013 年 5 月 14 日		会议地点: 北京大学人民医院第 15 会议室		
伦理委员会 审 评 意 见	同 意	作必要修改后同意	不同意	修改后重申
		✓		
	修改知情同意书:			
	1. 统一“操作项目”名称; 2. 详细介绍“操作步骤”; 3. 解释“随机”, 建议优化“分组名称”; 4. 详细告知取血检测项目; 5. “关于费用”单列, 明确告知免费项目; 6. 补充受试产品的不良反应及处理措施; 7. 补充此试验尚需遵循《医疗器械临床试验规定》; 8. 修改文字错误。			
主任委员 (副主任委员) 签字:  2013 年 5 月 17 日				

**Reply Letter to the " Consent after modification " Project from
the Ethics Committee**

After re-examination by the Medical Ethics Committee of our hospital, Professor Yi Feng, the project leader, revised the Informed Consent Form (Version 1.0) of the project 《Acupuncture balanced anesthesia used in abdominal operation and its protective effects》 according to the opinions of the Ethics Committee on May 14, 2013. The revised Informed Consent Form (Version 2.0) meets the requirements of the Ethics Committee.

Agree to start clinical research.

Chairman:

Date:

北京大学人民医院医学伦理委员会

“修改后同意”项目伦理审查回复函

经我院医学伦理委员会再次审查,项目负责人冯艺教授根据2013年5月14日伦理委员会审查意见,对《针药复合麻醉在腹部手术的应用及机体保护效应》项目的知情同意书 (Version 1.0) 进行了修改,修改后的知情同意书 (Version 2.0) 符合伦理委员会要求,同意开始临床研究。

主任委员: 
2013年6月3日