the Ethical Approval Form

（scan version）

附件 24
Appendix 24

首都医科大学附属北京佑安医院

伦理通知函（第六版）

BEIJING YOUAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY NOTIFICATION OF ETHICAL REVIEW（6th version）

2004 年 08 月 30 日修订 Revised

尊敬的教授 Dear professor：李宁

您提交的研究方案经我院伦理委员会审查的结果如下：

The protocol submitted by you has been reviewed by our Ethics Committee and the result is as following:

会议编号/日期 Meeting No./Date	2005-01/ 2005 年 1 月 20 日	会议地点 Meeting Place	医院 B 楼 8 层会议室
伦理委员会批件号 Review No. of Ethics Committee	京佑科伦字 2005[02]号	审查类别 Review Type	☐紧急会议审查 Emergency Convened EC Conference ☒会议审查 Convened EC Conference ☐快速审查 Expedited Review
研究方案名称/编号 Name of protocol/No.	北京市肝癌临床数据与样本资源库发展与应用研究		
申办者 Sponsor	北京市科学技术委员会		
所属专业组 Specialty	/	主要研究者 Principal Investigator	李宁
CFDA 批件号（如果适用）Research project Approval No. by the CFDA(if applicable)			
回避 EC 委员 EC members who shy away from the project review	☐有 Yes ，请描述 Please describe：_____ ☒无 No		

审查文件（含版本号/版本日期）如下 The documents for review (including version No / version date.) are as follows：

（1）课题实施方案 版本号：无 版本日期 2004 年 2 月

（2）知情同意书 版本号：1.0 版本日期 2005-01-10

1. 伦理委员会对该试验/研究给出的评审意见和建议 The review opinions to the trial/research by the Ethics Committee:

知情同意书部分内容及用语需修改和明确：

①尽量明确标本会以何种方式使用，检测项目，将来检测数据哪些会告知研究者等；

②本研究涉及国际合作，基因检测，应说明生物标本是否出境，如不出境，需声明，如需出境，需办理相关批准手续；

③受益条款中，所列受益与受试者无关，如促进规范化等，应明确实在的写出受试者受益；

④研究者团队中应增加临床负责收集病例研究者，并由相应研究者作为相关问题联系人；

⑤签字处应增加受试者、研究者的联系电话。

2. 伦理委员会对该该试验/研究的审查结果如下（在□内划×）
The review decisions on the trial/reseach by the Ethics Committee are as follows (mark × in the □)

同意 Approval □	作必要的修正后同意 Post-revision approval ☒	作必要的修正后重审 Re-review after revision □	不同意 Disapproval □	终止/暂停 Termination /Suspension □

3. 若同意 If approval，
批准日期 Approval Date：_____；批准时限 Approval Period：_____；本批件失效日期 Expire Date:：_____

4.如果是“作必要的修正后同意”，则：

“作必要的修正后同意”指的是基本上同意，但是根据伦理委员会的审查建议，仍需做一些无需伦理委员会再次审查的修改。请按照伦理委员会的意见和建议对方案和(或)知情同意书等文件进行详细修改后，送交药物临床试验机构/科研处/医务处进行修改情况复核，以上 3 个部门将负责修改后的审查。复核通过后将药物临床试验机构/科研处/医务处出具的复核意见表和送交复核的文件资料一并递交伦理委员会，上述工作宜在伦理审查后的 20 个工作日内完成。对于“作

必要修正后同意”的研究，审批当日就是机构办公室主任/科研处处长/医务处处长确认获得审批的必要修改已经修改的日期。

If “Post-revision approval”:

“Post-revision approval” means it is approved basically but some modifications are still needed without review again according to the EC. If it comes to Post-revision approval, please submit the documents to the Drug Clinical Trial Organization Office / Scientific Research Division / Department of Medical Administration for re-check after complementing and revising in details according to the opinions and suggestions of the Ethics Committee, The 3 departments above are responsible for the review of revision. If it passes the re-check, please submit the documents for re-check and the re-check opinion presented by the Drug Clinical Trial Organization Office / Scientific Research Division / Department of Medical Administration, the above work should be completed in 20 workdays after ethic review. For the Post-revision approval project, the approval date is the date on which the director of Drug Clinical Trial Organization Office / Scientific Research Division / Department of Medical Administration confirms the required modifications for approval has been done.

送交复核的文件资料为 the documents submitted for re-check：

（1）修改之处的清单列表 List of all modifications

（2）修改后的方案（如果适用）Modified protocol (if applicable)

（3）修改后的知情同意书（如果适用） Modified Informed Consent document(s) (if applicable)

（4）伦理委员会的修改意见 Opinions and suggestions of the Ethics Committee

（5）修改后的其他材料 Other modified documents

5. 如果是作必要修正后再审或终止/暂停

“作必要的修正后重审”与“作必要的修正后同意”很不一样，“作必要的修正后重审”意味着试验/研究必须再次递交伦理委员会，再次审查，就像一个新的试验/研究的审查一样。请按照伦理委员会的意见和建议对方案、知情同意书等文件进行补充或详细修改后，送交伦理委员会再次审查。在这种情况下，所有的修改将被直接递交至伦理委员会，以便再次审查。秘书负责预先审查该试验/研究是否已经根据伦理委员会的修改意见和建议进行了修改，如果已经进行了修改，满足了要求，可以准备会议审查。

If it comes to Re-review after revision or Termination/Suspension：

“Re-review after revision” is quite different from “Post-revision approval”. It means the trial/research must be submitted to and reviewed again like a new

trial/research by the EC. Please submit the protocol、informed consent form and so on to the Ethics Committee for review again after complementing and revising in details according to the opinions and suggestions of the Ethics Committee. In this case all modifications revision will go back directly to the EC for re-review. The secretary is responsible for pre-review that whether the trial/research has been revised according to the opinions and suggestions of the Ethics Committee, and then prepare the meeting if it meet the requirements.

再次送审时请递交以下文件 Please submit the following documents when review again：

（1）递交材料清单 List of all submitted documents

（2）伦理申请表 The Application Table for Ethical Review

（3）伦理审查推荐表 The Recommendation Form for Ethical Review

（4）修改之处的清单列表（包括（但不限于）：①修改的内容及修改原因；②修改方案对预期风险和受益的影响；③修改方案对受试者权益与安全的影响。）List of modification(include (but not include): ①the revised content and reason; ② the influence of revised protocol to the expectant risk and benefit; ③ the influence of revised protocol to the participant's benefits and safety.)

（5）修改后的病例报告表和原始病历（如果适用）Modified Case Report Form and original medical records (if applicable)

（6）修改后的知情同意文件（如果适用）Modified Informed Consent document(s) (if applicable)

（7）修改后的招募广告和其他招募材料（如果适用）Modified Advertisement(s) and other recruitment materials (if applicable)

（8）修订后的方案（如果适用）Modified protocol (if applicable)

（9）修改后的其他材料 Other modified documents

6. 该研究进行过程中将接受伦理委员会的跟踪审查？
Will the research process accept follow-up review of the ethics committee?

是 Yes ☒	否 No ☐

7. 如果接受伦理委员会的跟踪审查，则：
if yes, that:

跟踪审查频度为研究批准之日起每 12 个月一次。

The tracking review frequency will be once every12month(s) since the approval date of the research.

但是伦理委员会有根据实际进展情况改变跟踪审查频度的权利。

But the ethics committee has the right to change the frequency of follow-up

review according to the actual progress.

请根据跟踪审查频度，按时向伦理委员会递交阶段报告。Please submit the progress report to the Ethics Committee according to the tracking review frequency。

8. 如果主要研究者对 EC 的审查结果有疑问，需要申诉，请联络医院伦理委员会，并提交书面申诉意见，详细说明申诉理由。

If the PI has some doubts about the EC review result and needs to appeal against the decision, please contacts the hospital's EC, and submits a written appeal proposal, and describes the reason of appeal in details.

9. 在开展试验/研究之前，请携带着“通知函”通知药物临床试验机构/科研处/医务处。 Please take the notification to notify the Organization Office of Drug Clinical Trial/Scientific Research Division/Department of Medical Administration before you start the trial /research.

伦理委员会联系方式 Contact information of Ethics Committee	科研项目 Scientific study	孟 莎：010-83997022 Meng Sha: 010-83997022
	临床试验项目 Clinical trial	盛艾娟：010-83997560 010-83997028 Sheng Aijuan: 010-83997560 010-83997028

主任委员签名：
Signature of the Chair:

伦理委员会（盖章）：
Ethics Committee (seal):

2005 年 1 月 20 日
2005Year 1Month 20Day