附件 24

首都医科大学附属北京佑安医院

伦理通知函（第四版）

BEIJING YOUAN HOSPITAL, CAPITAL MEDICAL UNIVERSITY

NOTIFICATION OF ETHICAL REVIEW（4th version）

2011 年 11 月 1 日修订 Revised

尊敬的教授 Dear professor：段钟平、郑素军

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	2012-04	会议地点 Meeting Place	/
伦理委员会批件号 Review No. of Ethics Committee	京佑伦字科[2012]42 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 Rreview
研究方案名称/编号 Name of protocol/No.	甘肃定西丙型肝炎病毒感染患者临床特点与机制研究		
申办者 Sponsor	--		
所属专业组 Specialty	--	主要研究者 Principle Investigator	段钟平、郑素军
SFDA 批件号（如果适用） Research project Approval No. by the SFDA(if applicable)	--		

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

（1）研究方案 第 2 版 2012-04-05

（2）知情同意书第 2 版 2012-04-05

1. 伦理委员会对该研究方案给出的评审意见和建议 The review opinions to the protocol by the Ethics Committee:

无

2. 伦理委员会对该研究方案的审查决定如下（在☐内划×）

The review decisions on the protocol by the Ethics Committee are as follows (mark × in the ☐)

同意 Approval ☒	作必要修正后同意 Post-revision approval ☐	作必要修正后再审 Re-review after revision ☐	不同意 Disapproval ☐	终止/暂停 Termination /Suspension ☐

若同意 If approval，
批准日期 Approval Date：2012-6-7；批准时限 Approval Period：12 个月；本批件失效日期 Expire Date：2013-6-6

如果是作必要修正后再审或终止/暂停，请按照伦理委员会的意见和建议对方案进行补充或详细修改后，送交伦理委员会再次审查。

If it comes to Re-review after revision or Termination/Suspension, please submit the protocol to the Ethics Committee for review again after complementing and revising in details according to the opinions and suggestions of the Ethics Committee.

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

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

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

（3）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; ②the influence of revised protocol to the expectant risk and benifit; ③ the influence of revised protocol to the participant'benifits and safety.)

（4）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)

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

（6）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)

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

（8）修改后的其他材料 Other modified documents

4. 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 ☐

如果接受伦理委员会的跟踪审查，则：if yes, that:

5. 审查频度为研究批准之日起每 12 月一次。
The review frequency will be once every 12 month(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.

伦理委员会联系方式 Contact information of	科研项目 Scientific study	孟 莎：010-83997022 Meng Sha: 010-83997022

Ethics Committee	临床试验项目 Clinical trial	盛艾娟：010-83997560 Sheng Aijuan: 010-83997560

主任委员签名：
Signature of the Chair:

伦理委员会（盖章）：
Ethics Committee (seal):

2012 年 6 月 7 日
2012 Year 6 Month 7 Day

注意 Note：

1.“同意”的研究应遵循已经伦理委员会批准的方案执行，应符合 SFDA/GCP 和《赫尔辛基宣言》的原则。

The “Approval” research shall be implemented following the protocol approved by the ethics committee, and conform to the principles of SFDA/GCP and Declaration of Helsinki.

2.“作必要修正后同意”方案，申办方/PI 按照伦理审查意见修改后，由机构办公室（临床试验）或科研处（基金资助项目）核实方可实施。

The “post-revision approval” protocol shall be modified according to the review opinions and it can be conducted after being checked by institution office(clinical trial) or science department.

3.“作必要修正后再审”的研究方案在提交复审方案前，应按评审意见进行逐条修改并在修改处做出标记或说明，修改后的研究方案连同初审意见一并递交伦理委员会申请复审。

The “Re-review after revision” protocol shall, before submitting the protocol for review again, be revised one by one and the revisions shall be marked or explained according to the review opinions. The revised protocol together with the initial review opinions shall be submitted to the ethics committee for review again.

4..“不同意”、“暂停”或“终止”的研究方案，申办者和研究者可就伦理委员会的意见及建议中提及的问题做书面申诉，并陈述理由。伦理委员会可就申诉作重新审查。

For the “Disapproval”, “Termination” or “Suspension” protocol, the applicants and investigators may appeal in writing aiming at the opinions of the ethics committee and the problems mentioned in the suggestions and state the reasons. The ethics committee may review again to the appeal.

5.研究过程中，对研究方案和知情同意书等相关文件所作的任何修改，均须得到伦理委员会审查同意后方可实施。

During the research process, any revisions made to the documents related to the protocol and informed consent can’t be implemented before obtaining the approval from the ethics committee.

6.本中心发生的严重不良反应事件或意外事件需在向 SFDA 上报的同时向伦理委员会作书面报告，伦理委员会有权对其评估做出新的决定。

The serious adverse events or accidents occurred in this centre shall be reported in writing to the ethics committee while reporting to SFDA, because the ethics committee has the right to make new decision on its evaluation.