Sample 1

香港中文大學醫學院
Faculty Of Medicine
The Chinese University Of Hong Kong

醫院管理局
新界東醫院聯網
Hospital Authority
New Territories East Cluster

Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee
香港中文大學-新界東醫院聯網 臨床研究倫理 聯席委員會

8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, HK
Tel : (852) 2632 3935 / 2144 5926 Fax : (852) 2646 6653 Website : http://www.crec.cuhk.edu.hk

The Joint CUHK-NTEC CREC is an independent committee established by CUHK/NTEC and authorized to perform ethics and scientific review and oversight of clinical studies within the jurisdiction of CUHK/NTEC in accordance with its standard operating procedure and the principles of the Declaration of Helsinki and ICH Good Clinical Practice.

CREC Ref. No.: 2006.425-T

14 MAY '14

To: Prof. Wai Sang POON
Dept. of Surgery
Prince of Wales Hospital

This notice is issued by the Joint CUHK-NTEC CREC with respect to the application/submission by you, being the principal investigator of the following study at your study site:

- **Study Protocol Title:** Autologous Mesenchymal Stem Cell Therapy Trial in Stroke Patients
- **Investigator(s):** Wai Sang POON, Hoi Tung WONG, Kent Kam Sze TSANG, Xian Lun ZHU, Gang LU, Anil Tejbhan AHUJA, George Kwok Chu WONG, Ho Keung NG, Ka Sing WONG

In accordance with our standard operating procedure, we have duly performed ethics and scientific review of your application/submission as detailed below:

- **Nature of Your Application/Submission:** ☐ Initial application ☐ Amendments/changes ☐ Others: ☒ Renewal
- **Mode of Review:** ☐ Full review ☒ Expedited review
- **Date of Initial/Renewal Approval:** 25 May 2014
- **Document(s) Reviewed:** See Schedule 1
- **Reviewer(s):** See Schedule 2

After due review by our reviewer(s), we hereby write to inform you of our decision on your application/submission as follows:

- **Decision:**
  - ☒ Application/Submission approved
  - ☐ Application/Submission approved with condition(s) (see condition(s) below)
  - ☐ Application/Submission approved with remark(s) (see remark(s) below)
  - ☐ Application/Submission approved with condition(s) and remark(s) (see condition(s) and remark(s) below)
- **Regular Progress Report(s) Required:** Every 12 months from the date of initial/renewal approval and during the period of the study if required

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Tel : (852) 2632 3935 / 2144 5926 Fax : (852) 2646 6653 Website : http://www.crec.cuhk.edu.hk

14 NOV '14

You, being the principal investigator of the study at your study site, are reminded to comply with our requirements and to maintain communication with us during the period of the study by undertaking the principal investigator's responsibilities including (but not limited to):

- if the study is an industry-sponsored clinical study, submitting to us a copy of the fully executed indemnity agreement satisfying the Hospital Authority's requirement prior to commencement of the study (if it has not been submitted yet);
- observing and complying with all applicable requirements under our standard operating procedure ("IRB/REC SOP"), the Declaration of Helsinki and the ICH GCP (if applicable);
- submitting regular progress report(s) at the required intervals (as specified above) in accordance with the requirements in the IRB/REC SOP;
- not implementing any amendment/change to any approved study document/material without our written approval, except where necessary to eliminate any immediate hazard to the subjects or if an amendment/change is only of an administrative or logistical nature;
- notifying us of any new information that may adversely affect the rights, safety or well-being of the subjects or the proper conduct of the study;
- reporting any deviation from the study protocol or compliance incident that has occurred during the study and may adversely affect the rights, safety or well-being of any subject in accordance with the requirements in the IRB/REC SOP;
- submitting safety reports on all SAEs observed at your study site or SUSARs reported from outside your study site in accordance with the requirements in the IRB/REC SOP; and
- submitting a final report in accordance with the requirements in the IRB/REC SOP upon completion or termination of the study at your study site.

In addition to the above, you are also reminded to observe and comply with other applicable regulatory and management requirements including (but not limited to):

- if required by Hong Kong laws or regulations, obtaining a certificate for clinical trial through the Hong Kong Department of Health and complying with the associated requirements;
- obtaining the necessary consent from the management of your institution/department in accordance with the requirements of your institution/department;
- if required by local laws or regulations at conducting site out of IRB/REC's jurisdiction, obtaining an approval and complying with associated requirements;
- not representing to any third party or in any way likely to mislead any third party forming the view that the approval from the IRB/REC has any extraterritorial effect; and
- with due diligence ensuring your teams, staff, agents or whosoever connected with you to comply with the preceding requirements.

Yours sincerely,

Envy Lee (Secretary)
for and on behalf of
The Joint CUHK-NTEC CREC

EL/ci

CREC Ref. No.: 2006.425-T

Sample 1

14 MAY '14

Schedule 1
Documents Reviewed

The documents reviewed by with respect to the said application/submission include:

(Not Applicable)

Schedule 2
Reviewers List
Joint CUHK-NTEC Clinical Research Ethics Committee

Title and Name	Occupation	Qualification	Male / Female (M/F)
Prof. Brian TOMLINSON	Professor, Department of Medicine and Therapeutics, CUHK	BSc, MBBS, MD, MRCP(UK), FHKCP, FRCP, FRC(E), FRCP(G), FHKAM(Med), FCP, FACP	M
Dr. Simon K.C. CHAN	Consultant, Department of Anaesthesia and Intensive Care, PWH	MBBS (UNSW), FANZCA(Aust), FHKCA, FHKAM, Dip Pain Mgt(HKCA), MHSM(UNSW)	M

Sample 2

Date: 06/30/2017

Address : Asan Medical Center 88, OLYMPIC-RO 43-GIL, SONGPA-GU, SEOUL 05505, KOREA TEL : 02-3010-7166, FAX : 02-3010-7318

Review Results Notification

Review Results Notification Date	10/27/2016

Receipt No.	S2016-1612-0001					
Project No	2016-1139					
Protocol Name	Risk factors for postoperative recurrence after primary bowel resection in patients with Crohn's disease					
Principal Investigator	Organization	General surgery	Position	Professor	Name	Chang-Sik Yu
Sponsor	Organization	IIT				
Detailed Classification of Research	The Bioethics and Safety Act					
	Research Target					
	Classification of Research					
	Research Phase					
Review Type	New Clinical Research Protocol					
Review Results	Results in which the start, continuation and change of research are possible	■ Approval ☐ Continue the Research As Previously Conducted				
	Results that must apply for supplementary review	☐ Approved with Modification ☐ Re-Review After Modification ☐ Continue the research but supplementation is needed. ☐ Continue the research but discontinue the research procedures subsequently implemented to a subject ☐ Early Termination of Approved Research ☐ Disapproval		☐ Approved with Conditions ☐ Rejection ☐ Continue the research but discontinue recruitment of new subjects ☐ Temporary Discontinuation of Approved Research ☐ Actions on the Researcher ☐ Other		

Sample 2

Date: 06/30/2017

		☐ Supplementation	
Submitted Date of Document	09/29/2016	**Review Date**	10/20/2016
Continuation Review Cycle	☐ 3 Months ☐ 6 Months ■ 1 Year ☐ Exemption ☐ Other	**Expiration Date of Approval**	10/19/2017

Review Opinion

This board had decided to approve as a result of reviewing the new protocol which the researcher has submitted. Thank you for presenting opinions after sincerely replying on the opinions presented by review members at the pre-review. All replies presented have been accepted in this meeting.

Risk Level Evaluation : Level I

List of Submitted Materials & Version No.

Protocol(Korean)(Ver 2)

CRF (Ver 1)

Institutional Review Board/Institutional Bioethics Committee Chairperson Moo-Song Lee (Seal)

* This Institutional Review Board complies with the related laws such as ICH, KGCP or Bioethics and Safety Act. In case of having a member at a conflict of interest relationship with this research, the corresponding member has been excluded from the review

Sample 3

中国医学科学院北京协和医院
伦理审查委员会审核证明

编号：S-234

项目名称	肠易激综合征症状发作规律以及按需治疗的研究		
项目来源	国家“十一五科技支撑计划”		
项目单位	消化内科	项目负责人	方秀才
审查方式	□书面审查 ☑会议审查	审核日期	2009-7-7
审查意见	本项目设计方案科学，受试者风险/受益合理，知情同意书符合伦理要求。		
结　　论	通过伦理委员会审查。		
注意事项	本审核结果只涉及对伦理问题的审核结论，如相关研究要求办理相应的手续，如到上级部门办理审批/备案手续，或按医院要求需要签署合同书/协议书的，请在项目开展前先行办理上述手续。		

伦理委员会主任委员：　陈杰

（签字）：

中国医学科学院北京协和医院
伦理审查委员会

中国医学科学院北京协和医院
伦理审查委员会

2009 年 7 月 7 日

Sample 4

INSTITUTIONAL REVIEW BOARD STATEMENT

Name of Journal: *World Journal of Gastrointestinal Surgery*

Manuscript NO: 35571

Manuscript Type: Clinical Practrice Study

Risk factors for pancreatic fistula following pancreaticoduodenectomy: A retrospective study in a Thai tertiary center

Narongsak Rungsakulkij, Somkit Mingphruedhi, Pongsatorn Tangtawee, Chonlada Krutsri, Paramin Muangkaew, Wikran Suragul, Penampai Tannaphai, Suraida Aeesoa

Institutional review board statement: this study was reviewed and approved by the Ramathibodi Hospital Institution Review Board, ID # 12-59-50

Name: Narongsak Rungsakulkij

Signature:

Date: 13 September 2017

Sample 4

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
๒๗๐ ถนนพระราม ๖ แขวงทุ่งพญาไท เขตราชเทวี กทม. ๑๐๔๐๐
โทร. (๐๒) ๒๐๑-๑๐๐๐

Faculty of Medicine Ramathibodi Hospital, Mahidol University.
270 Rama VI Road, Ratchathewi, Bangkok 10400, Thailand
Tel. (662) 201-1000

Documentary Proof of Ethical Clearance
Committee on Human Rights Related to Research Involving Human Subjects
Faculty of Medicine Ramathibodi Hospital, Mahidol University

MURA2016/818/N1

Title of Project (EC_600199)	Risk Factors and Perioperative Complications Following Pancreaticoduodenectomy: A Thai Tertiary Care Experience
Protocol Number	ID 12-59-50
Principal Investigator	Narongsak Rungsakulkij, M.D.
Official Address	Department of Surgery Faculty of Medicine Ramathibodi Hospital Mahidol University
New Title 1: (Approval : 20/04/2017)	Risk Factors of Postoperative Pancreatic Fistula Following Pancreaticoduodenectomy: A Thai Tertiary Care Experience

The aforementioned project has been reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, based on the Declaration of Helsinki.

Signature of Chairman Committee on Human Rights Related to Research Involving Human Subjects	..... Asst. Prof. Chusak Okascharoen, M.D.
Date of Approval	December 30, 2016
Duration of Study	4 Months