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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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

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

분당서울대학교병원 생명윤리심의위원회
Tel : 82-31-787-7800, 8000
Fax : 82-31-787-8869
경기도 성남시 분당구 구미로 173번길 82 (우) 13620

본 위원회에서 승인된 모든 연구자들은 다음의 사항을 준수하셔야 합니다.

1. 연구계획서 및 변경계획서의 승인 이전에 연구대상자의 해당 임상연구의 참여 금지됩니다.

2. 승인 받은 계획서에 따라 연구를 수행하여야 합니다. 변경계획서에 대한 승인 이전에 원 임상연구 계획서와 다른 임상연구의 실시는 금지됩니다.

3. IRB 승인 받은 동의서를 사용하여야 합니다.

4. 연구대상자에게 강제 혹은 부당한 영향이 없는 상태에서 충분한 설명에 근거하여 동의과정을 수행할 것이며, 잠재적인 연구대상자에게 연구에의 참여여부를 고려할 수 있도록 충분한 기회를 제공하여야 합니다.

5. 연구진행에 있어 연구대상자를 보호하기 위해 불가피한 경우를 제외하고 연구의 어떠한 변경이든 위원회의 사전승인을 받고 수행하여야 합니다. 연구대상자들의 보호를 위해 취해진 어떠한 응급상황에서의 변경도 즉각 위원회에 보고하여야 합니다.

6. 연구대상자에게 발생한 즉각적 위험 요소의 제거가 필요하여 원 계획서와 다르게 연구를 실시해야하는 경우, 연구대상자에게 발생하는 위험요소를 증가 시키거나 연구의 실시에 중대한 영향을 미칠 수 있는 변경사항, 예상하지 못한 중대한 이상약물/의료기기 반응에 관한 사항, 연구대상자의 안전성이나 임상 연구의 실시에 부정적인 영향 을 미칠 수 있는 새로운 정보에 관한 사항은 위원회에 신속히 보고하여야 합니다.

7. 위원회의 승인을 받은 연구대상자 모집 광고문을 사용해야 합니다.

8. 위원회의 승인은 1년을 초과할 수 없습니다. 1년 이상 연구를 지속하고자 하는 경우에는 반드시 연차지속보고를 하여야 합니다.

9. 심의결과가 승인이 아닌 경우에는 답변서를 제출하여야 하며, 심의일로부터 6개월 이내에 이루어져야합니다.

10. 위원회가 연구를 반려하는 경우 이의신청을 할 수 있으며, 같은 사항에 대하여 2번 연속으로 이의 신청은 할 수 없습니다.

11. 연구종료 시에는 종료 및 결과보고서를 작성하여 제출해야 합니다.

12. 생명윤리 및 안전에 관한 법률, 약사법/의료기기법, 헬싱키 선언 및 ICH-GCP 가이드라인 등 국내외 관련 법규를 준수하여야 합니다.

13. 헬싱키선언에 따라 모든 임상시험은 첫 연구대상자를 모집하기 전 공개적으로 접근이 가능한 데이터베이스 (primary registry)에 연구에 대하여 공개하여야 하며, 예를 들어 http://register.clinicaltrials.gov 를 이용하실 수 있습니다. 상세한 내용은 IRB 홈페이지를 참고하십시오.

14. 승인 받은 연구에 대하여 기관의 내부 점검 및 외부의 실태조사를 받을 수 있습니다. 기관의 내부 점검자, 외부의 모니터요원 및 점검자, 규제기관의 실태조사자 등이 연구 관련 문서(전자문서 포함)에 대한 열람을 요청하는 경우 연구담당자는 이에 적극 협조해야 합니다.

분당서울대학교병원 생명윤리심의위원회

Sample 5

Tel : 82-31-787-8001-8002
Fax : 82-31-787-8869
경기도 성남시 분당구 구미로 173번길 82 (우) 13620

HRPP SOP ver2.6_2015.05.15/e-IRB 2015.05.15

심의결과통보서

IRB No.	B-1406/254-004	제출경로	분당서울대학교병원		
연구 과제명	(국문)	췌장암에 대한 내시경초음파유도하 세침흡인술 후 바닥 및 덮개 슬라이드 검체 사이의 진단적 정확도에 대한 비교			
	(영문)	Comparison of the Diagnostic Accuracy between Base and Cover Slide Smear after Endoscopic Ultrasound Guided Fine Needle Aspiration for Pancreatic Cancer			
	Protocol No.		Version No.	3.0	
연구자		성명	소속	직위	전공분야
	책임연구자	김재환	내과	교수(진료교수이상)	소화기내과
	의뢰기관				
생명윤리 및 안전에 관한 법률에 따른 분류	☐ 인간대상연구 ■ 인체유래물연구 ☐ 배아줄기세포주이용연구 ☐ 배아연구 ☐ 체세포복제배아연구 ☐ 단성생식배아연구 ☐ 배아생성의료기관 ☐ 인체유래물은행				
연구 종류	임상시험 외 연구	☐ 증례보고 ☐ 생태학적 연구 ☐ 단면조사 연구 ☐ 조사,설문,인터뷰 연구 ☐ 환자군 연구(case series) ☐ 환자-대조군연구 ☐ 인체유래물 저장소 연구 ☐ 등록(레지스트리)연구 ☐ 시판후사용성적조사(PMS) ☐ 전향적 코호트 연구 ☐ 후향적 코호트 연구 ■ 기타 (인체유래물 연구)			
	임상시험	연구대상	☐ 의약품 ☐ 생물학적제재 ☐ 화장품 ☐ 건강기능식품 ☐ 의료기기(분류번호(등급):) ☐ 기타 ( )		
			일반명: EUS-FNA 슬라이드 검체 / 상품명: 해당사항 없음		
		Phase	☐ 제 1 상 ☐ 제 1/2 상 ☐ 제 2 상 ☐ 제 2/3 상 ☐ 제 3 상 ☐ 제 4 상 ☐ 생물학적동등성 ☐ PMS 연구 ☐ Phase 분류 없음 ☐ 기타 ( )		
		식약처 승인 대상 여부	☐ 식약처 승인 대상 ☐ 승인 제외 대상 * 식약처 승인 절차 진행 중인 경우 추 후 식약처 승인서 제출 바랍니다.		
		임상시험 목적	☐ 학술용 ☐ 국내(KFDA)허가용 ☐ 해외 허가용 (국가명 :)		
연구계획서승인일	2014년 06월 20일	정기보고주기	1년		
승인유효 만료일	~ 2016년 06월 19일 까지	연구위험도	low risk		
심의대상	종료보고서	심의종류	☐ 정규심의(회의차수:) ■ 신속심의 ☐ 긴급심의		
접수일자	2016년 04월 25일	심의일자	2016년 04월 27일		
심의결과통보일	2016년 04월 27일				
심의목록	종료보고				
심의결과	승인				

Result: Approval

본 통보서에 기재된 사항은 분당서울대학교병원 생명윤리심의위원회의 기록된 내용과 일치함을 증명합니다.
본 생명윤리심의위원회는 생명윤리 및 안전에 관한 법률, 약사법, 의료기기법 및 ICH-GCP등 관련 법규를 준수합니다.
본 연구와 이해관계(Conflict of Interest)가 있는 위원이 있을 경우 연구의 심의에서 배제하였습니다.

분당서울대학교병원 생명윤리심의위원회
Tel : 82-31-787-8001-8002
Fax : 82-31-787-8869
경기도 성남시 분당구 구미로 173번길 82 (우) 13620

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생 명 윤 리 심 의 위 원 회 위 원 장

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研究計畫許可書

計畫編號：IRB104-94-A
計畫名稱：食道擴張引發食道反應的機制: GABA-B 接受體在食道化學敏感性的角色
計畫主持人：佛教慈濟醫療財團法人花蓮慈濟醫院 內科部 陳健麟主任
計畫預計執行期限：January/01/2015 to December/31/2016
計畫文件版本日期：【**Protocol：Version 3, 10/26/2015；ICF：Version 3, 10/26/2015**】
上述計畫業經本院研究倫理委員會於 **2015** 年 **10** 月 **27** 日審查同意，本委員會的運作符合優良臨床試驗準則及政府相關法律規章。
本研究計畫許可書有效期限自 **2016** 年 **01** 月 **01** 日至 **2016** 年 **12** 月 **31** 日止，計畫主持人須依國內相關法令及本會規定通報嚴重不良反應事件及非預期問題，並應於到期日至少 6 週前提出期中報告，經本會審核通過，方可繼續執行。

Certificate of Approval

REC No.：IRB104-94-A
Title of Protocol： Mechanisms of distension-induced esophageal reflex: roles of GABA-B receptors on esophageal chemosensitization
Principal Investigator：Chien-Lin Chen / Department of Medicine, Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation
The protocol is approved by the Research Ethics Committee of Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation on **October/27/2015**. The committee is organized under, and operates in accordance with, the Good Clinical Practice guidelines and governmental laws and regulations.
This approval is valid from **January/01/2016 to December/31/2016**. The investigator is required to report Serious Adverse Events and Unanticipated Problems in accordance with the governmental laws and regulations and REC of Hualien Tzu Chi Hospital, Buddhist Tzu Chi Medical Foundation requirements and apply for a continuing review not less than six weeks prior to the approval expiration date.

Chien-Hsing Wang, M.D.
Chairman, Research Ethics Committee

佛教慈濟醫療財團法人花蓮慈濟醫院
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計畫主持人應辦及注意事項如下：

（一）經本委員會核准之受試者同意書已加蓋本會戳章如附件，請複印以進行知情同意程序且善盡保護受試者之責任，並將受試者同意書副本給予受試者留存，本會將不定期進行監測，請務必確實執行。

（二）受試者招募廣告須先至本會加蓋戳章後方可張貼。

（三）請遵守人體試驗管理辦法第十五條規定「醫療機構於人體試驗期間，不得對外發表成果或為宣傳」。

（四）經本委員會核准之計畫案於執行過程中，任何內容之變更須向本委員會申請變更案審查，審查通過才能再度執行。若發生任何嚴重不良事件，請依「人體試驗管理辦法」及「藥品優良臨床試驗準則」之規定向中央主管單位和本委員會通報。

（五）執行過程中，任何可能危害受試者安全、影響試驗執行之新發現或影響研究倫理委員會同意試驗繼續進行之情事，須向本會報告。

（六）執行期間請每一年繳交一次期中報告，以利本會進行審查，審核通過後，方可繼續執行，若該研究已完成，則請直接繳交結案報告；核准有效期限屆滿，若尚未通過本會之期中報告追蹤審查，試驗不得繼續，且本會將拒絕該主持人申請之新案審查，若逾期二個月仍未完成繳交，則視同主持人放棄，本會將逕自予以撤案。

（七）若計畫需展延研究期限，須於執行期限到期日六週前檢送計畫變更展延申請至本會審查，審核通過後，方可繼續執行；若計畫許可書有效日期已過，該計畫即不得申請展延且須依本會規定繳交報告。

（八）研究計畫中止或終止時，請依規定向本委員會提出申請。

（九）試驗完成後，請於結束後三個月內繳交結案報告。

（十）若未遵守以上規定，本會可以取消此研究計畫許可書之有效性，且可能影響您未來送審計畫之權益，敬請配合。

佛教慈濟醫療財團法人花蓮慈濟醫院研究倫理委員會 2015/10/27 謹啟