附件 **1：**

中山大学-约翰霍普金斯大学

临床研究协调员（**Coordinator**）培训课程介绍

一、课程目标

通过在线课程学习和现场培训，培养出一批符合国际临床研究标准的临床研究协调员，组建一支高素质的临床研究协调员队伍。具体目标包括：

- 熟悉临床研究法规、管理规范以及基本流程；
- 掌握重要的临床研究伦理规范；
- 熟悉临床研究相关文件管理；
- 掌握临床研究协调中关键环节及常见问题的处理；
- 培养出能协助研究者开展高水平临床研究的临床研究协调员。

二、主要内容

- 临床研究伦理问题（Ethics in Clinical Research & Case Study Review）；
- 临床研究设计及方案（Protocol Trial Design and the Study Protocol）；
- ICH（International Conference on Harmonization）指南及研究文档建立（ICH Guidelines and Document Set Up）
- 知情同意书设计（Introduction to Informed Consent and Consent Design）
- 不良事件监测与报告（Adverse Event Detections and Reporting）
- 研究质量控制（QA/QC）（Quality Assurance and Quality Control）

课程内容和时间安排的初步计划见附录一和附录二。

三、培训形式

包括在线课程和现场课程两大部分：

1.在线课程（Online course）：

第二期在线课程时间为 2 月 10 日至 3 月 16 日。

课程包括 4 部分内容：（1）完成调查问卷；（2）上传英文自我介绍视频；（3）观看临床研究教学视频模块及完成前后测试；（4）用英语书面回答有关课程学习体会的问答题。教学视频 JHUSOM 的专家教师录制专门的，共 6 节，每节课视

频教学约 20 分钟，课程前后各有简短的测试。初选学员登录教学网站，自主安排时间完成课程学习及所有要求的内容。

2.现场课程（Onsite course）：

第二期现场课程时间为 3 月 27 日至 3 月 31 日。

由 JHUSOM 的专家教师现场授课。授课内容主要为临床研究协调关键内容及实践应用，结合具体临床研究案例进行讲解及小组讨论。课程第一天和最后一天分别进行测验，课程最后一天内容为讲者答疑及学员交流。

四、教学特色

- 在线课程和现场课程相结合：在线课程内容简明扼要，注重巩固理论基础，主要目的是让学员掌握临床研究相关基础概念及熟悉英文术语，为现场课程学习做准备；现场教学注重实践应用，结合案例进行详细讲解及小组讨论；
- 小班授课教学：现场课程学员总数约 24 人，集中五天授课，上午进行理论学习及小组讨论，下午进行附属医院视察及小组讨论；
- 师资力量：授课教师为约翰霍普金斯大学医学院（Johns Hopkins University School of Medicine, JHUSOM）具有丰富临床研究和教学经验的临床研究协调者，提供在线课程及现场讲座，学员与讲者可互动讨论；
- 教学形式多样：包括在线课程学习、现场课程学习、案例分析、实地考察等。

五、考核和结业

由 JHUSOM 专家组成的考核小组对学员进行遴选和考核。

（一）根据以下在线课程考核指标，择优筛选 24 名学员进入现场课程：

1. 学员按时完成所有在线课程的学习；
2. 英文自我介绍视频的评分；
3. 每个教学视频后的测试题成绩；
4. 书面作答的评分。

（二）通过以下现场课程考核指标者，由 JHUSOM 授予结业证书：

1. 出勤情况：按时参加课程并签到应达到 90%以上；
2. 课堂表现：由各组带教老师根据学员对理论知识的掌握度、参与度以及课题改进程度进行评分，评定为合格；
3. 课程测试：课程结束时测试评分为合格。

六、核心讲者

- **Edward J. Fuchs, PA-C, MBA,** Division of Clinical Pharmacology, the Johns Hopkins University School of Medicine (JHUSOM). He graduated from Pennsylvania State University and Towson University in 1984. Got the M.B.A. Of Medical Services Management in the Johns Hopkins University in 2001. He's been working on HIV-related clinical researches in JHU since 1984, and is experienced in clinical research coordination and investigation.

- **Hongxia Li, MS, MBBS,** Depatment of Pediatric GI/Nutrition, Johns Hopkins Medical Institute. She graduated from China Medical University in 1995, and got MS degree of Information Systems in 2002 and MS degree of Epidemiology in 2011 from University of Maryland, Baltimore County (UMBC). She has over eight years of experience in clinical research including Phase I/II/III trials initiation, coordination, IRB submission and regulatory management, data management and quality management.

附录一　在线课程内容

内容	简要内容
Research Ethics	This module will provide a brief overview of the history of clinical research ethics, and how past scientific conduct has led to current research regulation. The ICH Good Clinical Practice (GCP) Guidelines will be introduced using the fundamental concepts of the Belmont Principles. Examples of how research coordinators apply research ethics to their everyday work will be presented.
Informed Consent	This module will provide a basic review of the requirements of informed consent as presented in the ICH E6 Good Clinical Practice :Consolidated Guidance.
GCP	This module will focus on the Essential Documents needed to demonstrate the compliance of the study team with the standards of GCP. Research Coordinators will receive several document templates, as well as the recommended checklist of documents from the ICH guidelines. The coordinators will learn how to create and use certain types of documents, and will at the end of the lecture be able to identify all of the types of documents needed for a particular study visit interaction through two case study examples.
Clinical Trial Design and Protocol	This module will be started with a brief introduction to the concept of clinical trial and low and high risk clinical trials. The presenter will also review the basic principles of designing clinical trials and types of clinical trial designs with advantages/disadvantages of each design. Most of the presentation will be given to review the elements of a clinical trial protocol from the study coordinator's perspective and discuss the importance of conducting research activities in compliance with the protocol.
QA/QC; Auditing and Monitoring	This module first defines and presents the regulatory background for quality assurance and quality control mechanisms. Second, conside -rations are explored for the design and implementation of these tools. Third, auditing and monitoring conventions are applied to the concept of quality, to demonstrate the importance of QA/QC in clinical trial design, practice, and oversight. Examples of QA are presented using basic SOP examples. Examples of QC approaches are demonstrated by using various methods, including checklists and logs.
Adverse Events	This module will introduce the concept of recognition and classification of adverse events based on applying ICH Good Clinical Practice Guidelines to the study protocol. Definitions and categorization of serious and unexpected adverse events, and requirements for reporting them to the research ethics committee will be reviewed. Sample case studies will be presented and the research coordinator’s role in identification, classification, and reporting of adverse events will be discussed.

附录二 现场授课内容和时间安排

INTRODUCTION TO CLINICAL RESEARCH: A ONE-WEEK INTENSIVE COURSE，
Johns Hopkins University School of Medicine And Sun Yat Sen University

	Thursday	Friday	Saturday	Sunday	Monday
9:00 am	**Introduction** Pre-Test Research Coordinator Training Expectations/ Goals Li & Fuchs	**Ethics Summary & PharmaSchool Quiz** Fuchs & Li	**Protocol /ICHSummary& PharmaSchoolQuiz** Li & Fuchs	**Consent/AE Summary & PharmaSchool Quiz** Fuchs & Li	**Privacy Issues in Clinical Research** Taylor
		Protocol Design & Case Studies Li	**Informed Consent & Case Studies** Li	**Discussion ofGuided Study Unit** Li & Fuchs	
10:00 am	**Ethical Considerations in Trials with Research Volunteers** Fuchs	**ICH GCP Study Documents & Case Studies** Fuchs	**Adverse Events & Case Studies** Fuchs	**Quality Assurance and Quality Control & Case Studies** Li	**Brief Content Review and Post-Test** Fuchs & Li
11:00 am	**Ethics Case Studies** Small Group Discussion Fuchs				
12:00	LUNCH	LUNCH	LUNCH	LUNCH	LUNCH AND REVIEW OF POSTTEST
1:00 pm	**Research Coordination at Johns Hopkins** Li & Fuchs	**Regulatory Issues/IRB** Pettit	**Small Group Case Studies** Instructor-Guided	**Informed Consent** Taylor	**Instructor Office Hours** Li & Fuchs
2:30	**Comparing Research Coordination Practices between Johns Hopkins and SYSU** (JHU/SYSU Train the Trainer Panel)	**Managing Your Own Data** Data Collection Data Quality Data protection Boland		**Case studies Ethics** Vitamin A Studies Pettit Taylor	
3:30 pm-5:00	**Small group interview**		**Small group interview**		