**Fundamental GCP Training**

**Srinagarind Hospital, Faculty of Medicine, Khon Kaen University**

**Day 1: 17 Feb 2015**

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| **Time** | **Topics** | **Speakers** |
| 8.00-8.30 | Registration | |
| 8.30-8.40 | Opening |  |
| 8.40-9.10 | Direction of Clinical Research Participation | Deputy Dean of Research Affairs |
| 9.10-10.00 | Principle of ICH GCP | Pichet Kamolrungsantisuk  พิเชฐ กมลรุ่งสันติสุข |
| 10.00-10.15 | Break | |
| 10.15-10.45 | Role & Responsibility of Ethics Committee | TBD |
| 10.45-11.15 | Role of Clinical Research Unit, KKU | Assoc.Prof. Kwanchanok Yimtae, M.D.  Director of Academic Clinical Research Office (ACRO)  รศ.พญ.ขวัญชนก ยิ้มแต้  ผู้อำนวยการ สถานบริหารจัดการงานวิจัยคลินิก |
| 11.15-11.45 | Role & Responsibility of Investigator | TBD |
| 11.45-12.00 | Q&A | |
| 12.00-13.00 | Lunch | |
| 13.00-13.30 | Research Protocol & Protocol Compliance | Siriphen Chunharas  ศิริเพ็ญ ชุณหรัศมิ์ |
| 13.30-14.00 | Role & Responsibility of Sponsor and CRO | Siriphen Chunharas  ศิริเพ็ญ ชุณหรัศมิ์ |
| 14.00-14.45 | Panel Discussion : Investigator, EC, ACRO and Sponsor | |
| 14.45-15.30 | Workshop #1 Patient Eligibility | |
| 15.30-15.45 | Break | |
| 15.45-16.30 | Group Presentation & Discussion | |

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**Day 2: 18 Feb 2015**

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| **Time** | **Topics** | **Speakers** |
| 8.30-09.00 | Informed Consent Form | Pichet Kamolrungsantisuk  พิเชฐ กมลรุ่งสันติสุข |
| 09.00-09.30 | Data Collection and Data Management | Narumol Benjamin  นฤมล เบญจมินทร์ |
| 09.30-10.00 | Monitoring | Prathana Anattiwong  ปรารถนา อาณัติวงศ์ |
| 10.00-10.15 | Break | |
| 10.15-11.15 | Workshop # 2 Informed Consent Process | |
| 11.15-12.00 | Group presentation | |
| 12.00-13.00 | Lunch | |
| 13.00-13.30 | Investigational drug handling | Narumol Benjamin  นฤมล เบญจมินทร์ |
| 13.30-14.00 | Safety Report (AE, SAE & SUSAR) | Prathana Anattiwong  ปรารถนา อาณัติวงศ์ |
| 14.00-14.30 | Quality Assurance (Audit & Inspection) | Pichet Kamolrungsantisuk  พิเชฐ กมลรุ่งสันติสุข |
| 14.30-14.45 | Break | |
| 14.45-15.45 | Workshop # 3 Safety Reporting | |
| 15.45-16.30 | Group Presentation | |
| 16.30-16.45 | Summary | |
| 16.40 | Closing remark | |