AF 01-12/1.0

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| à¹à¸à¸ à¸²à¸à¸­à¸²à¸à¸à¸°à¸¡à¸µ à¸à¹à¸­à¸à¸§à¸²à¸¡**KamphaengphetRajabhat University****Research Ethics Committee** |  **Resubmission Form** **for Ethical Review** |

1. Please fill in this form and provide necessary documents that apply. This form will help exemption or expedite the review process.

|  |  |
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| **Section 1 : Protocol identification****Request for 🗆 Exemption or 🗆 Expedited Review, please specify the criteria category …………. (see the criteria for exemption and expedited review) 🗆 Full Board Review.** | **REC No. ………….** |
| **For board use only** |
| 1.1 | Protocol title (Thai) |  |  |
| 1.2 | Protocol title (English) |  |  |
| 1.3 | Sponsor/Source of funding Government ……………………… NGO …………………………..  Private sector …………………….. Others ………………………….  |  |  |
| 1.4 | Protocol number (if any) |  |  |
| 1.5 | Sponsor contact phone/fax (Thailand)/e-mail |  |  |
| 1.6 | Protocol as part of - Thesis / Dissertation / IS / Undergraduate No Yes(Attach doc 6.11) |  |  |
|  |  - Postgraduate training (Board/Sub-board) No Yes(Attach doc 6.11) |  |  |
| **Section 2: Investigator** (attach doc 6.5) |  |  |
| 2.1 | Name of principal investigator |  |  |
| 2.2 | Degree/Specialty  |  |  |
| 2.3 | Institutional affiliation  |  |  |
| 2.4 | Contact phone/Fax/Email  |  |  |
| 2.5 | How many other research projects are still open under your responsibility?  |  |  |
| 2.6 | How many active research subjects are under your responsibility?  |  |  |
| 2.7 | How many research staffs (Co-investigators included) do you have for thisproject ? |  |  |
| **Section 3: Research protocol** |  |  |
| 3.1 | Research Design (Check all that apply) |  |  |
|  | Basic science research |  |  | Descriptive/Qualitative |  |  |  |  |
|  | Survey |  |  | Case-control  |  |  |  |  |
|  | Laboratory experiment  |  |  | Diagnostic test |  |  |  |  |
|  | Applied research  |  |  | Clinical trial |  |  |  |  |
|  | R/D |  |  | Cohort |  |  |  |  |
|  | Bioequivalence |  |  | Other (specify)……………………... |  |  |  |  |
|  |  |  |  |
| 3.2 | Methods involved the followings (tick all that apply) |  |  |
|  |  | Questionnaire/Interview/Diary (Attach doc 6.6) |  |  |  |  |
|  |  | Specimen/Sample collection |  |  |  |  |
|  |  | Records/Document extraction |  |  |  |  |
|  |  | In vitro diagnostic devices |  |  |  |  |
|  |  | In vivo diagnostic devices |  |  |  |  |
|  |  | Medical devices (Attach doc 6.12, 6.13, 6.14) |  |  |  |  |
|  |  | Drugs(Attach doc 6.10, 6.12,6.15) |  |  |  |  |
|  |  | Cosmetics(Attach doc 6.10, 6.12) |  |  |  |  |
|  |  | Medicinal plants(Attach doc 6.10, 6.12,6.15) |  |  |  |  |
|  |  | Foods(Attach doc 6.12) |  |  |  |  |
|  |  | Behavioral/Psychological intervention |  |  |  |  |
|  |  | Embryonic stem cell/Genetic material |  |  |  |  |
|  |  | Radiation/Isotope |  |  |  |  |
|  |  | Tissue/Organ transplant |  |  |  |  |
|  |  | Procedures/Operation |  |  |  |  |
|  |  | Other (specify)………………………………… |  |  |  |  |
| 3.3 | Expected duration of the project………years………months |  |  |
| 3.4 | Investigation site |  |  |
|  |  | Single |  |  |  |  |
|  |  | National multi-site/multi-center |  |  |  |  |
|  |  | International multi-site/multi-center |  |  |  |  |
| 3.5 | Has this protocol been reviewed by another ethics committee prior to this submission? |  |  |
|  |  | No |  |  |  |  |
|  |  | Yes (Attach doc 6.17) |  |  |  |  |
| 3.6 | Has this protocol been registered according to clinical trial registration  |  |  |
|  |  | No |  |  |  |  |
|  |  | Yes (Attach doc 6.16, 6.18) |  |  |  |  |
| **Section 4: Subjects and recruitment** |  |  |
| 4.1 | Does this protocol include the following subjects? (tick all that apply) |  |  |
|  |  | No data obtained directly from human (Go to 4.2) |  |  |  |  |
|  |  | Prisoners  |  |  |  |  |
|  |  | Pregnant women/Elderly  |  |  |  |  |
|  |  | Mentally ill subjects |  |  |  |  |
|  |  | Chronic disease/Cancer or terminally ill subjects |  |  |  |  |
|  |  | Neonates/Infants/Children (aged <20) |  |  |  |  |
|  |  | HIV/AIDS |  |  |  |  |
|  |  | Institutionalized e.g. orphanage, leprosarian  |  |  |  |  |
|  |  | Illiterate subjects or Minorities e.g. hilltribes |  |  |  |  |
|  |  | Subordinate e.g. students, employees, soldiers, patientsOther (specify)…………………………………  |  |  |  |  |
|  |  |
| 4.2 | Methods used to recruit subjects |  |  |
|  |  | No (Go to 4.3) |  |  |  |  |
|  |  | Personal contact at outpatient clinic /inpatient  |  |  |  |  |
|  |  | Personal contact at ER or ICU |  |  |  |  |
|  |  | Personal contact in community |  |  |  |  |
|  |  | Contact via telephone or post |  |  |  |  |
|  |  | Advertising e.g. poster, flyers, mass media (website included) |  |  |  |  |
|  |  | Other (specify)…………………………………………… |  |  |  |  |
| 4.3 | Person obtaining informed consent |  |  |
|  |  | No (Go to 4.4) |  |  |  |  |
|  |  | Principal/Co-Investigators |  |  |  |  |
|  |  | Research staff |  |  |  |  |
|  |  | Other (specify) ........................................................... |  |  |  |  |
| 4.4 | Expected number of subjects in each arm............................. total number of subject………….……… |  |  |
| 4.5 | Subject payment/incentives |  |  |
|  |  | No  |  |  |  |  |
|  | Yes(if yes, please give details............................................................................... |  |  |  |  |
| 4.6 | Compensation for injury / lost |  |  |
|  |  | No |  |  |  |  |
|  | Yes(if yes, please give details............................................................................... |  |  |  |  |
| **Section 5 : Study monitoring or DSMB(Data Safety Monitoring Board)** |  |
|  |  | No |  |  |  |  |
|  |  | Yes |  |  |  |  |
| **Section 6: Summary of attached documents required for the review (please tick all that apply)** |
|  |  |  | copies |  |
| 6.1 | แบบยื่นขอรับการพิจารณาจริยธรรม (Submission form : AF 01-10)  | 🞏 | 4 |  |
| 6.2 | แบบประเมินโครงการวิจัยด้วยตนเอง(Self-Assessment Form : AF 02-10 หรือ AF 04-11) | 🞏 | 4 |  |
| 6.3 | ข้อมูลคำอธิบายและหนังสือแสดงความยินยอมสำหรับผู้เข้าร่วมโครงการวิจัย (Information sheet and/or consent form : AF 04-10, AF 05-10, AF 06-10)  | 🞏 | 4 |  |
| 6.4 | โครงการวิจัยฉบับเต็ม (Full Protocol)  | 🞏 | 4 |  |
| 6.5 | ประวัติผู้วิจัยหลักและผู้ร่วมวิจัย (Principal investigator and Co-investigator ’s CV)Human Subject Protection CourseGCP training certificate (clinical trial only)  | 🞏🞏🞏 | 4 |  |
| 6.6 | รายละเอียดเครื่องมือที่ใช้ในการวิจัย (Questionnaire/Scale/Interview Form/Case report form)  | 🞏 | 4 |  |
| 6.7 | การขัดแย้งทางผลประโยชน์(Conflict of Interest and Funding Form : AF 03-10) | 🞏 | 4 |  |
| 6.8 | งบประมาณที่ได้รับ โดยย่อ (Budget) | 🞏 | 4 |  |
| 6.9 | สรุปโครงการวิจัย (Protocol synopsis)  | 🞏 | 4 |  |
| 6.10 | Investigator brochure  | 🞏 | 4 |  |
| 6.11 | Approval document from thesis committee/advisor | 🞏 | 1 |  |
| 6.12 | Recruitment materials e.g. written information and script  | 🞏 | 1 |  |
| 6.13 | Medical devices safety approval from Thai FDA | 🞏 | 1 |  |
| 6.14 | Certificate of Free Sale | 🞏 | 1 |  |
| 6.15 | Approval for investigational drug used in research | 🞏 | 1 |  |
| 6.16 | Drug approval from Thai FDA | 🞏 | 1 |  |
| 6.17 | Approval result report from other IRB | 🞏 | 1 |  |
| 6.18 | Document of registration | 🞏 | 1 |  |
| 6.19 | Electronic files of all above and related documents | 🞏 | 1 CD ROM |  |

1. Note: Investigator has to provide document 6.1- 6.9 and 1 CD ROM (6.19) on submission for initial review. Other documents are also necessary for some type of protocol. Document 6.9 should be in Thai and not exceed 5 pages. Should you need more information, please contact our board secretary at KPRU-REC. Tel 0-55706555

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| Investigator signature ……………........................…...….................................dated…….....…..…/…...………/………….... (Please retain copy of the completed form for your study record.) |

1. **Please attach the electronic files of all required documents (6.1 – 6.18)**
2. **…………………………………………………………………………………………………………**

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| **โครงการวิจัยหมายเลข (REC No.) ...................../.....................****กรุณาอ้างอิงหมายเลขข้างต้นเมื่อต้องการติดต่อกับ คณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยราชภัฏกำแพงเพชร****หมายเลขโทรศัพท์ 055 706555 ต่อ** 2333 |