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, patients  Other (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 Course  GCP 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 |