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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 1 : Protocol identification**  **Request for**  **Exempt Review**  **Expedited Review**  **Please specify the criteria number (s) that related to the requested category ………….**  **(see the criteria for exempt review or expedited review in SOP)** | | | | | | | **IRB No.** |
| **Remarks** |
| 1.1 | Protocol title (ไทย) | | | | | |  |
| 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  No  Yes  - Postgraduate training (Board/Subboard)  No  Yes | | | | | | Attach doc 7.2 |
| 1.7 | Protocol Registry   Yes, please indicate  ClinicalTrials.gov, number.………….....   Thai Clinical Trials Registry, number …………...   No | | | | | | Attach doc 7.21 |
| **Section 2: Investigator** (attach doc 7.13-7.14) | | | | | | |  |
|  | Name | | Degree/Specialty | GCP training certificate  Expired date | Institutional affiliation | email | Contact phone |
| PI |  | |  |  |  |  |  |
| Co-I |  | |  |  |  |  |  |
| Co-I |  | |  |  |  |  |  |
| Co-I |  | |  |  |  |  |  |
| 2.1 | How many other research projects are still active under PI responsibility? | | | | | |  |
| 2.2 | How many active research subjects are under PI responsibility? | | | | | |  |
| 2.3 | How many research staff (Co-Investigators included) do you have for thisproject? | | | | | | Attach CV & GCP training |
| **Section 3: Research protocol** | | | | | | |  |
| 3.1 | | Research Design (Check all that apply)   Basic science research  Descriptive study   Survey  Diagnostic study   Laboratory experiment  Case-Control study   Applied research  Cohort study   R&D  Cross-sectional study   Bioequivalence study  Interventional / Clinical Trials  Systematic Review   Other (please specify)……………………………………………………………………………………………………. | | | | |  |
| 3.2 | | Methods involved the followings (check all that apply)  Drugs   Medical devices   Radiation/isotope   Procedures/operation   Pathogen or animal toxin   Tissue/organ transplant   In vivo diagnostic devices   In vitro diagnostic devices   Specimen/sample collection   Questionnaire/interview/diary   Records/document extraction   Embryonic stem cell/genetic material   Behavioral/psychological intervention   Other (specify)……………………………………………………………………  | | | | | Attach doc 7.14, 7.18, 7.19  Attach doc 7.14, 7.16  Go to section 6  Attach doc 7.9 |
| 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 7.20 |
| **Section 4: Subjects and recruitment** | | | | | | |  |
| 4.1 | | Does this protocol include the following subjects? (check all that apply)  No data obtained directly from human   Prisoners   Pregnant women   Mentally ill subjects   Cancer or terminally ill subjects   Neonates/infants/children (aged <18)   HIV/AIDS   Institutionalized e.g. orphanage, leprosarium   Illiterate subjects or Minorities e.g. hilltribes   Subordinate e.g. students, employees, soldiers  | | | | | Go to 4.2 |
| 4.2 | | Methods used to recruit subjects  No data obtained directly from human   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)……………………………………………  | | | | | Go to 6 |
| 4.3 | | Person obtaining informed consent  No informed consent applied   Principal/Co-Investigators   Research staff   Other (specify) ...........................................................  | | | | | Go to 4.4 |
| 4.4 | | Expected number of subjects ………….......................................................... | | | | |  |
| 4.5 | | Subject payment/incentives  No   Yes   if yes, please give details............................................................................... | | | | |  |
| 4.6 | | Compensation for injury / loss, Insurance  No   Yes   if yes, please give details............................................................................... | | | | |  |
| **Section 5 : Study monitoring or DSMB** **(Data Safety Monitoring Board)**  No   Yes  | | | | | | |  |
| **Section 6: Biosafety Checklist**  **Please check the appropriate box(es) relating to the project.**   The project involves at least one of the following, In this case, please submit the documents to the institutional biosafety committee (IBC) for consideration.   The project involves infectious or potentially infectious pathogens (biosafety level 2 or above) to humans or animals, animal toxins (level 2) (please refer to the levels of risk in pathogens and animal toxins list in ประกาศกระทรวงสาธารณสุข เรื่อง รายการเชื้อโรคที่ประสงค์ควบคุม ตามมาตรา 18 พ.ศ. 2560 และรายการพิษจากสัตว์ที่ประสงค์ควบคุม ตามมาตรา 19 พ.ศ. 2560) (www.ibc.research.chula.ac.th หัวข้อกฎหมายและคู่มือ)   The project involves genetically modified (recombinant) DNA or RNA.   The project involves genetically modified organism(s), animal(s), insect(s), plant(s), cell line(s) or cell(s) using exchange of genetic materials (recombinant DNA or RNA) from different species which pose potential biological risk or hazard.   The project does not involve any of the above. | | | | | | | |
| **Section 7: Summary of attached documents required for the review (please check all that apply)** | | | | | | |  |
| 7.1 | | Cover letter for ethical review with signature of Chairperson/Department head of PI  | | | | | หัวหน้าสังกัดเป็นผู้ลงนาม |
| 7.2 | | Application letter from outsiders to contact research in the faculty/hospital  | | | | | หัวหน้าสังกัดเป็นผู้ลงนาม |
| 7.3 | | Approval document from thesis committee/advisor  | | | | | ประธานหลักสูตรเป็นผู้ลงนาม |
| 7.4 | | Submission form  | | | | | ผู้วิจัยหลักเป็นผู้ลงนาม |
| 7.5 | | Self-Assessment form  | | | | | ผู้วิจัยหลักเป็นผู้ลงนาม |
| 7.6 | | Conflict of interest (COI) and funding form  | | | | | ผู้วิจัยหลักเป็นผู้ลงนาม |
| 7.7 | | Conflict of interest for Co-Investigator  | | | | | ผู้วิจัยร่วมแต่ละท่านเป็นผู้ลงนาม |
| 7.8 | | Protocol synopsis  | | | | |  |
| 7.9 | | Full protocol  | | | | |  |
| 7.10 | | Information sheet   Consent form   Or Letter for retrospective medical record review  | | | | |  |
| 7.11 | | Questionnaire/scale/interview form/CRF/Diary cards and other  | | | | |  |
| 7.12 | | Materials to be used for the recruitment of potential research participants (Poster)  | | | | |  |
| 7.13 | | Budget  | | | | |  |
| 7.14 | | Investigator brochure (Clinical trials) / Product Information (Medical device)  | | | | |  |
| 7.15 | | Recruitment materials e.g. written information and script  | | | | |  |
| 7.16 | | Medical devices approval from Thai FDA  | | | | |  |
| 7.17 | | Certificate of Free Sale  | | | | |  |
| 7.18 | | Approval for investigational drug used in research  | | | | |  |
| 7.19 | | Drug approval from Thai FDA  | | | | |  |
| 7.20 | | Approval result report from other IRB  | | | | |  |
| 7.21 | | Document of registration  | | | | |  |

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| Investigator signature ……………........................…......................................................................................... Date…….....…..…/…….....…..…/…….....…..…  (……………………………...Name - Surname………………………….) |