Please fill in all the items this form and provide necessary documents that apply. This form will help quickening 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/website)** | | | | | | | **IRB No.** |
| **Remarks** |
| 1.1 | Protocol title (ไทย) | | | | | |  |
| 1.2 | Protocol title (English) | | | | | |  |
| 1.3 | Sponsor/Source of funding  Self-funded/None   Government, Please specify……………………………  NGO, Please specify ………………………………………   Private sector, Please specify.………………………….  Others, Please specify …………………………………..   Funded internally by Faculty of Medicine, Chulalongkorn University, Please specify.……………………………… | | | | | |  |
| 1.4 | Sponsor Protocol code, Please specify.………………………….   None | | | | | |  |
| 1.5 | Sponsor contact phone/fax (Thailand)/e-mail, Please specify.………………………….   None | | | | | |  |
| 1.6 | Protocol as part of - Thesis / Dissertation  No  Yes  - Postgraduate training (Board/Subboard)  No  Yes | | | | | |  |
| 1.7 | Protocol Registry   Yes, please indicate  Clinicaltrials.gov, Number……...  Thai Clinical Trials Registry, Number……...   No | | | | | |  |
| **Section 2: Investigators** | | | | | | |  |
|  | 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 human participants are under PI responsibility? | | | | | |  |
| 2.3 | How many research staff (Principal Investigator and Co-Investigators included) do you have for thisproject? | | | | | | Attach update CV & GCP training |
| **Section 3: Research protocol** | | | | | | |  |
| 3.1 | | Research Design (Check all that apply)  Descriptive study   Basic science research  Case-control study   Survey  Diagnostic study   Laboratory experiment  Cross-sectional study\*   Applied research  Interventional/Clinical trials\*   R/D  Prospective Cohort study\*   Bioequivalence study  Retrospective Study   Systematic review Other (specify)…………………….......... | | | | | \*For investigator-initiated study, note “AF 06-18 Biostatistics Consulting Form” from Biostatistics Consulting is required for Prospective Cohort study, Cross-sectional study, Interventional / Clinical Trials |
| 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)……………………………………………………………………  | | | | |  |
| 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: Participants and recruitment** | | | | | | |  |
| 4.1 | | Does this protocol include the following participants? (check all that apply)  No data obtained directly from human   Prisoners   Pregnant women   Mentally ill participants   Cancer or terminally ill participants   Neonates/infants/children (aged <18)   HIV/AIDS   Institutionalized e.g. orphanage, Leprosarium   Illiterate participants or Foreigners e.g. hilltribes   Subordinates e.g. students, employees, soldiers   Other (specify)……………………………………………  | | | | | Go to 4.2 |
| 4.2 | | Methods used to recruit participants  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 Materials e.g. poster, flyers, social media (website included)   Recruitment via online platform (specify)……………………………………………   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 participants ………….......................................................... | | | | |  |
| 4.5 | | Participant 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   if yes, please specify the details of the DSMB composition............................................................................... | | | | | | |  |
| **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 participants 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  | | | | | Signed by Head/Chairperson |
| 7.2 | | Application letter from outsiders to contact research in the faculty/hospital  | | | | | Signed by Head/Chairperson |
| 7.3 | | Approval document from thesis committee/advisor  | | | | | Signed by Program director |
| 7.4 | | Submission form  | | | | | Signed by Principal Investigator |
| 7.5 | | Self-Assessment form  | | | | | Signed by Principal Investigator |
| 7.6 | | Funding form  | | | | | Signed by Principal Investigator |
| 7.7 | | Conflict of interest for Investigator  | | | | | Signed by Principal Investigator and each co-investigator(s) |
| 7.8 | | Protocol synopsis  | | | | |  |
| 7.9 | | Full protocol  | | | | |  |
| 7.10 | | Information sheet   Consent form   Or Letter asking for retrospective medical record review   Or Letter on permission granted for EMR or data/specimen usage from hospital director/owner  | | | | | International student intending to conduct research outside Thailand is not required to submit Information Sheet and Consent form |
| 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  | | | | |  |
| 7.22 | | Note from MDCU Biostatistics Consulting | | | | |  |

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