NU-IRB# ……..……………….. AF 01-12/5.0

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|  | **Institutional Review Board**  **Naresuan University** | **Resubmission Form for Ethical Review** |

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, please specify the criteria category\_\_\_\_\_(see the criteria for exemption and expedited review) | | | | | | | | | | | | | | | | | | |
| □ | Expedited Review, please specify the criteria category\_\_\_\_\_(see the criteria for exemption and expedited review) | | | | | | | | | | | | | | | | | | |
| □ | Full Board Review | | | | | | | | | | | | | | | | | | |
| 1.1 | Protocol title (Thai) | | | | | | | |  | | | | | | | | | | | | | | |
| 1.2 | Protocol title (English) | | | | | | | |  | | | | | | | | | | | | | | |
|  | Protocol number (if any) | | | | | | | |  | | | | | | | | | | | | | | |
| 1.3 | Sponsor/Source of funding | | | | | | | | □ | | Government | | | | | | | | (please specify) | | | | |
|  |  | | | | | | | | □ | | Private sector | | | | | | | |
|  |  | | | | | | | | □ | | NGO | | | | | | | |
|  |  | | | | | | | | □ | | Others | | | | | | | |
| 1.4 | Sponsor contact | | | | | | | | Phone | | |  | | | | | | | E-mail | |  | | |
| 1.5 | Protocol as part of | | | | | | | | | | | | | | | Yes | | No | (if yes, please specify) | | | | |
|  | * Thesis/Dissertation/IS/Undergraduate | | | | | | | | | | | | | | | □ | | □ |
|  | * Postgraduate training (Board/Sub-board) | | | | | | | | | | | | | | | □ | | □ |
| **Section 2: Investigator (**☑**)** | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1 | Name of principal investigator | | | | |  | | | | | | | | | | | | | | | | | |
| 2.2 | Degree | | | | |  | | | | | | | | | | | | | Specialty (if applicable) | | | | |
| 2.3 | Institutional affiliation | | | | |  | | | | | | | | | | | | | | | | | |
| 2.4 | Contact phone# | | | | |  | | | | | | | | | | | | | E-mail | |  | | |
| 2.5 | Numbers of research projects are still open under your responsibility | | | | | | | | | | | | | | | | | |  | | | | |
| 2.6 | Numbers of active research subjects are under your responsibility | | | | | | | | | | | | | | | | | |  | | | | |
| 2.7 | Numbers of Co-investigators included and research staffs for this project | | | | | | | | | | | | | | | | | |  | | | | |
| **Section 3: Research protocol (**☑**)** | | | | | | | | | | | | | | | | | | | | | | | |
| 3.1 | Research Design (☑ all that apply) | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | Basic science research | | | | | | | | | | | □ | | Case-control study | | | | | | | |
|  | □ | | Laboratory experiment | | | | | | | | | | | □ | | Cohort study | | | | | | | |
|  | □ | | Research and Development (R&D) | | | | | | | | | | | □ | | Clinical trial | | | | | | | |
|  | □ | | Bioequivalence | | | | | | | | | | | □ | | Descriptive/Qualitative | | | | | | | |
|  | □ | | Diagnostic test | | | | | | | | | | | □ | | Survey | | | | | | | |
|  | □ | | Applied research | | | | | | | | | | | □ | | Other (specify)......................................... | | | | | | | |
| 3.2 | Methods involved the followings (☑ all that apply) | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | Questionnaire/Interview/Diary | | | | | | | | | | | □ | | In vivo diagnostic devices | | | | | | | |
|  | □ | | Records/Document extraction | | | | | | | | | | | □ | | Medical devices | | | | | | | |
|  | □ | | Behavioural/Psychological intervention | | | | | | | | | | | □ | | Drugs | | | | | | | |
|  | □ | | Specimen/Sample collection | | | | | | | | | | | □ | | Cosmetics | | | | | | | |
|  | □ | | Radiation/Isotope | | | | | | | | | | | □ | | Medicinal plants | | | | | | | |
|  | □ | | Tissue/Organ transplant | | | | | | | | | | | □ | | Procedures/Operation | | | | | | | |
|  | □ | | Embryonic stem cell/Genetic material | | | | | | | | | | | □ | | Foods | | | | | | | |
|  | □ | | In vitro diagnostic devices | | | | | | | | | | | □ | | Other (specify).............................................. | | | | | | | |
| 3.3 | Expected duration of the project | | | | | | \_\_\_\_\_\_\_\_ | | | years | | | \_\_\_\_\_\_\_\_ | | months | | | | | | | | |
| 3.4 | Investigation site | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | Single | | | | | | | | | | | □ | | Multi-center | | | | | | | |
|  |  | |  | | | | | | | | | | | | | □ | | National | | | | □ | International |
| 3.5 | Has this protocol been reviewed by another ethics committee prior to this submission? | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No | | | | | | | | | | | □ | | Yes | | | | | | | |
| 3.6 | Has this protocol been registered according to clinical trial registration | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No | | | | | | | | | | | □ | | Yes | | | | | | | |
| **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 | | | | | | | | | | | □ | | HIV/AIDS | | | | | | | |
|  | □ | | Pregnant women/Elderly | | | | | | | | | | | □ | | Institutionalized e.g. orphanage, leprosarian | | | | | | | |
|  | □ | | Mentally ill subjects | | | | | | | | | | | □ | | Illiterate subjects or Minorities e.g. hilltribes | | | | | | | |
|  | □ | | Chronic disease/Cancer or terminally ill subjects | | | | | | | | | | | □ | | Subordinate e.g. students, employees, soldiers, patients | | | | | | | |
|  | □ | | Neonates/Infants/Children (aged <20) | | | | | | | | | | | □ | | Other (specify).............................................. | | | | | | | |
| 4.2 | Methods used to recruit subjects | | | | | | | | | | | | | □ | | Not applicable (Go to 4.3) | | | | | | | |
|  | □ | | Personal contact at outpatient clinic /inpatient | | | | | | | | | | | □ | | Contact via telephone or post | | | | | | | |
|  | □ | | Personal contact at ER or ICU | | | | | | | | | | | □ | | Advertising e.g. poster, flyers, mass media (website included) | | | | | | | |
|  | □ | | Personal contact in community | | | | | | | | | | | □ | | Other (specify)...................................................... | | | | | | | |
| 4.3 | Person obtaining informed consent | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No (Go to 4.4) | | | | | | | | | | | □ | | Research staff | | | | | | | |
|  | □ | | Principal/Co-Investigators | | | | | | | | | | | □ | | Other (specify)...................................................... | | | | | | | |
| 4.4 | Expected number of subjects in each group | | | | | | | \_\_\_\_\_\_\_\_ | | | | | | total number of subject | | | | | | \_\_\_\_\_\_\_\_\_\_ | | | |
| 4.5 | Subject payment | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No | | | | | | | | | | | □ | | Yes …………..…. Bath/participant | | | | | | | |
| 4.6 | Subject incentives | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No | | | | | | | | | | | □ | | Yes …………..…. Bath/participant | | | | | | | |
| 4.7 | Compensation for injury/lost | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No | | | | | | | | | | | □ | | Yes …………..…. Bath/participant | | | | | | | |
| **Section 5: Study monitoring or DSMB (Data Safety Monitoring Board) (**☑**)** | | | | | | | | | | | | | | | | | | | | | | | |
|  | □ | | No | | | | | | | | | | | □ | | | Yes | | | | | | |
| **NOTE:** | | NA = Not applicable | | | | | | | | | | | | | | | | | | | | | |

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|  |  |  |  |
| Principal Investigator signature |  | Date | ........................................... |
|  | ( ) |  |  |

For attach document please see Checklist submission for investigator

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| **ที่อยู่ สำนักงานคณะกรรมการจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร** | | | | |
| กลุ่ม 1 | กลุ่มสาขาวิชาวิทยาศาสตร์สุขภาพ | | | กองการวิจัยและนวัตกรรม งานจัดการมาตรฐานและเครือข่าย คณะกรรมการจริยธรรมการวิจัยในมนุษย์ ชั้น 4 อาคารมหาธรรมราชา มหาวิทยาลัยนเรศวร  เลขที่ 99 หมู่ 9 ตำบลท่าโพธิ์ อำเภอเมืองพิษณุโลก จังหวัดพิษณุโลก 65000 |
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| กลุ่ม 3 | กลุ่มสาขาวิชาวิทยาศาสตร์ทางการแพทย์ | | | สำนักงานคณะกรรมการจริยธรรมการวิจัยในมนุษย์ กลุ่มสาขาวิชาวิทยศาสตร์  ทางการแพทย์ ชั้น 3 อาคารสิรินธร โรงพยาบาลมหาวิทยาลัยนเรศวร  เลขที่ 99 หมู่ 9 ตำบลท่าโพธิ์ อำเภอเมืองพิษณุโลก จังหวัดพิษณุโลก 65000 |
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