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 |
| โทร. | 055-968752 | อีเมล | nu-irb-board1@nu.ac.th |
| กลุ่ม 2  | กลุ่มสาขาวิชาวิทยาศาสตร์เทคโนโลยี มนุษยศาสตร์และสังคมศาสตร์ |
| โทร. | 055-968642 | อีเมล | nu-irb-board2@nu.ac.th |
| กลุ่ม 3  | กลุ่มสาขาวิชาวิทยาศาสตร์ทางการแพทย์ | สำนักงานคณะกรรมการจริยธรรมการวิจัยในมนุษย์ กลุ่มสาขาวิชาวิทยศาสตร์ทางการแพทย์ ชั้น 3 อาคารสิรินธร โรงพยาบาลมหาวิทยาลัยนเรศวร เลขที่ 99 หมู่ 9 ตำบลท่าโพธิ์ อำเภอเมืองพิษณุโลก จังหวัดพิษณุโลก 65000 |
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