**Mahidol University Central Institutional Review Board (MU-CIRB)**

**Research Project Submission Form**

**For Project Intervention**

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| --- | --- | --- |
| MU-CIRB ………..…. /………….….…. | Meeting Date............./................/............... | Topics No. ................................ |
| **Instructions:**   1. Please read the instructions carefully before filling in the form. 2. Please answer all questions in the Research Project Submission Form and be consistent with the designed research project. 3. If a section is not applicable to your research, mark “Not applicable”. 4. Please summarize your inputs in the form and specify where further details can be found, such as page number in the research proposal. 5. As you are filling in the digital copy of this form, remove all instructions in italics marked with red type (including these) so that they are not included in the final version. Specify the date of completing the form in the footer page. | | |

**1**. **Title of Research Project:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**2. Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Status** ❏ Affiliate Faculty \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Department\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Others, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Student from Faculty \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Department\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Bachelor Program ❏ Master Program ❏ Doctoral Program

**Contact address:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Telephone number:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **E-mail address:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Please attach a resume/curriculum vitae)*

* 1. **Experience and Training in Human Research Ethics** *\* Training should be refreshed every 3 years\**

Number of active protocols currently carried by the Principal Investigator **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Number of human subjects under the Principal Investigator’s responsibility \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Date of the recent training in human subject protection \_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏Covered in post-graduate curriculum ❏ CITI program ❏ Attending a workshop/conference\_\_\_\_\_\_\_\_\_\_\_\_

❏ Date of recent Good Clinical Practice (GCP) Training \_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Please attach the certificate of attendance/completion)*

* 1. **Please declare any Conflict of Interest with a funding agency**

❏ Nothing to declare ❏ Yes, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**3. Co-investigator(s)\*** *Provide information of all co-investigators following item 3.1, please submit their CVs as well as IRB certificate training. In the case of students, please indicate the name of the advisor as well,*

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| **3.1** | **Name:** | **Affiliate Faculty:** |
| **Contact address:** | |
| **Telephone number:** | **E-mail address:** |

**4.** **Experience and Training in Human Research Ethics** **of all members in this research project**

*\* Please attach the certificate of attendance/completion*

*\*Training should be refreshed every 3 years*

| **Status** | **Name** | **Experience and Training in Human Research Ethics** | **Training year (B.E.)** |
| --- | --- | --- | --- |
| **Principal Investigator** |  | ❏ Register for Ethics course in post-graduate curriculum  ❏ CITI program  ❏ Good Clinical Practice (GCP) Training  ❏ Other: specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| **Co- Investigator** | 1 | ❏ Register for Ethics course in post-graduate curriculum  ❏ CITI program  ❏ Good Clinical Practice (GCP) Training  ❏ Other: specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
| **Co- Investigator** | 2. | ❏ Register for Ethics course in post-graduate curriculum  ❏ CITI program  ❏ Good Clinical Practice (GCP) Training  ❏ Other: specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**5. Source (s) of Funding/ Sponsor(s), and Budget** (Information required for review and consideration)

🞏 No funding

🞏 Grant application submitted*(Once the grant is approved, please submit the document certifying funding support to MU-CIRB)*

🞏 Grant approved, awaiting contract signature *(Once the grant is approved, please submit the document certifying funding support to MU-CIRB)*

🞏 Grant approved, contract signed *(Once the grant is approved, please submit the document certifying funding support to MU-CIRB)*

Type of funding body **❏** University Fund **❏** Domestic Fund **❏** International Fund

Name of grant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of funding agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Duration of funding: from year\_\_\_\_\_\_\_ to year\_\_\_\_\_\_\_

Total budget amount: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Processed of funded-research contract:

❏ Via Research Management and Development Division, Office of President, Mahidol University

❏ Others, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Does the title of research project (as this MU-CIRB submission form) exactly same as the title of the funded project?

🞏 Yes, the exactly same title

🞏 No, please specify in details*............................................................................................................................*

*\* If the grant is approved, please submit the document certifying funding support to MU-CIRB to enable the Certificate of Approval (COA) to be issued.*

**6. Background & Rationale** *(Explain briefly)*

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**7. Objective of the Study** *(as mentioned in the proposal)*

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**8. Research Plan**

**8.1 Type of Research**

❏ Biomedical / Clinical Intervention Research

❏ Drug trial phase \_\_\_\_\_\_\_\_\_\_\_\_\_ Please specify this research drug’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Status of this drug ❏ registered drug ❏ investigational new drug

## *(In case of registered drug, please attach the details of drug registration or approval )*

❏ Medical device, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Status of this medical device ❏ registered ❏ investigational device

*(In case of registered, please attach the details of device registration or approval)*

❏ Vaccine trial phase \_\_\_\_\_\_\_\_\_\_\_\_\_ Please specify this vaccine’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Please attach the details of vaccine registration or approval )*

❏ Food ❏ Herb ❏Cosmetic Please specify this product’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Status of this product ❏ registered ❏ investigational

*(In case of registered, please attach the details of product’s registration or approval)*

**Testing method**

❏ Sensory evaluation test ❏ Safety test ❏ Efficacy test

**Research Design**

❏ Randomized parallel controlled trial ❏ Randomized cross-over controlled trial

❏ Randomized factorial trial ❏ Patient/Physician-preference trial ❏ Pre-post trial

❏ Cross-over trial (single group) ❏ Sensory test

❏ Pilot study ❏ Other: *please specify* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Social / Behavioral Research

|  |  |  |
| --- | --- | --- |
| * Descriptive study * Observational study * Retrospective study | * Participatory action research * Case-control study * Cross-sectional | * Qualitative research * Cohort study * Prospective study |
| * Pilot study |  |  |
| ❏ Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

❏ Surveillance, Monitoring*: please specify* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Repository (using stored materials: cells, tissue, and fluid)

❏ Secondary Research using stored data that require owner's approval

**8.2 Subject selection and allocation** *\* Please fill in the information briefly*

**8.2.1 Inclusion criteria**

1. ..........................
2. .........................

**8.2.2 Exclusion criteria**

1. ........................
2. .......................

**8.2.3 Withdrawal criteria** (for individual participant)

❏ None, because it is minimal-risk research

❏ If a research project is more than minimal risk, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**8.2.4 Termination criteria** (for the whole research project)

❏ None, because it is minimal-risk research

❏ If a research project is more than minimal risk, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**8.2.5 Subject allocation** (for more than 1-arm study)

❏ “No segmentation” (all participants were treated the same throughout the study)

❏ The participants were divided into 2 or more groups. Please specify the method used for grouping \_\_\_\_\_\_\_\_

**8.3 Sample size**

**-** For Biomedical Research, *please specify calculation method using formula and variables*

- For Social-Behavioral Research, *please provide rationale for estimating the adequate number of subjects for data collection*

**8.4 Vulnerability of human subjects to be recruited**

**❏** Vulnerable subjects

❏ Children ❏ Mentally disabled ❏ Chronic illness

❏ Other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Healthy volunteers (Note: Healthy elderly are categorized as healthy volunteers, while elderly with underlying health conditions or those requiring assistance must be classified as vulnerable subjects.)

**8.5 Replacement procedure if a subject withdraws from the study**

❏ Not necessary, because the number of subjects calculated already includes the drop-out number

❏ Will recruit new replacement subjects

**9. Intervention** *(Please delete irrelevant information)*

9.1 Details of intervention (Please tick the boxes  for all relevant items)

🞏 Herbal Products 🞏 Food 🞏 Cosmetics 🞏 Medical Devices

🞏 Other: please specify (e.g., robotics applications, exercise programs, manuals, teaching methods...

9.1.1 Herbal Products according to the Thai Herbal Products Act, B.E. 2562, such as herbal medicine and products derived from herbs.

Product Name....................................... Manufacturer..........

Production Method...............................................................................

Production Quality-Control Method...............................................................................

Herbal Substance Componentsได้แก่ ..............................

Active Ingredients ............................. Quantity of active ingredients per gram .......................................

🞏 Product is Registered with Registration No. ..... (Please attach proof of certification from Thai FDA and status "Active", e.g., letter of certification, or verified information from http://pca.fda.moph.go.th/service.php)

🞏 Product exists but is not yet registered; please attach supporting documents, e.g., herbal production facility license, results of contaminants, such as steroids, toxicology test results in laboratory animals, safety test results and adverse reactions in humans.

🞏 If the product is at the research and development (R&D) stage, please provide the relevant safety testing plan.

9.1.2 Food

🞏 Foods that are exempt from production authorization, e.g., meat, vegetables, fruit, beans, sugar, spices, flour, shrimp paste, eggs, coconut milk. Please specify ....................................Source of product................................

🞏 Food products that have been certified by the Food and Drug Administration (FDA).

Product Name........................... Food Serial Number (or FDA Code)................... Manufacturer....................

Components include.................................

🞏 Attach evidence of certification from the Thai FDA and status 'Active' (e.g., certification letter or verified information from http://pca.fda.moph.go.th/service.php)

🞏 Newly developed products not yet registered with the Thai FDA, not classified as a novel food, due to the use

of natural ingredients and food additives listed by the Thai FDA.

Product Name: .......................................... Manufacturer: .................. Production Method: .............................

Quality Control Method for Production: ....................................................................................

Components include: ..............................

🞏 Taste-tested once for sensory acceptance

🞏 Continual consumption (Please attach proof of safety, e.g., microbial tests for closed (sealed) container foods, heavy metal tests for powders or pellets)

🞏 Novel food products as per the Ministry of Public Health Announcement, e.g., extracts from plants or animals using non-aqueous solvents, parts of plants or animals with no history of consumption for less than 15 years, foods made from ingredients not listed by the Thai FDA, or foods using new production methods.

Product Name: .......................................... Manufacturer: .................. Production Method: ..........

Quality Control Method for Production: ....................................................................................

Components include: ..............................

Active ingredient(s): ......................................... Active ingredient(s); quantity per gram: .....................................

🞏 Taste-tested once for sensory acceptance

🞏 Continual consumption (Please attach evidence, such as:

🞏 Safety tests, e.g., microbial tests for closed (sealed) container foods, heavy metal tests for powders or pellets)

🞏 If there has been no previous testing in humans, please attach references to toxicology studies in experimental animals, e.g., acute toxicity, sub-chronic toxicity, or

🞏 In the case of prior human testing, please attach references to human testing results.)

🞏If the product is in the research and development (R&D) stage, please provide relevant safety testing plan.

9.1.3 Cosmetics

Product Name .......................................... Manufacturer .................. Production Method ………

Quality Control Method for Production ....................................................................................

Components include ..............................

Contains ingredients listed as substances that may be used in the manufacture of cosmetics according to the

announcement of the Ministry of Public Health, please specify……………… Amount per gram…….

🞏 Registered. Registration No. ...... (Please attach proof of certification from the Thai FDA and status 'Active', e.g., certification letter, or verified information from http://pca.fda.moph.go.th/service.php)

🞏 Not yet registered, please attach supporting documents, e.g., cosmetic production or import license, test results for ingredients, such as *Tagetes erecta* (marigold) flower extract, and the Ministry's concentration limits,

as well as results of irritation and sensitization tests in experimental animals, human tests, and any adverse reactions.

🞏 If the product is at the research and development (R&D) stage, please provide the relevant safety testing plan............................

9.1.4 Medical Devices as per the Medical Device Act, B.E. 2562

Product Name .......................................... Manufacturer .................. Production Method……….

Quality Control Method for Production ..................................................................................................

🞏 Medical device groups that require manufacturer or importer authorization, including surgical gloves, human- blood bags, surgical gloves, contact lenses, HIV-related diagnostic kits.

🞏 Medical device groups requiring detailed declaration, including physical therapy devices or products, devices for measuring alcohol levels, silicone breast implants, devices or equipment used externally to enhance or tighten breasts, kits to test for methamphetamine and amphetamine in urine, products with anti-wrinkle properties used in eye surgery.

🞏 Medical device groups requiring declaration: Other medical devices

Authorization Status

🞏 Registered, Authorization/Notification No. .......... (Please attach proof of certification from the Thai FDA and status 'Active', e.g., certification letter, or verified information from http://pca.fda.moph.go.th/service.php)

🞏 Not yet registered

Risk Category

🞏 1 Low risk 🞏 2 Moderate risk, low level 🞏 3 Moderate risk, high level 🞏 4 High risk

Please attach supporting documents, e.g., medical device production or import license, evidence of biological evaluation results of medical devices, e.g., cases of embedded materials that have post-implantation biological evaluation reports (MOH.2395 clinical trial research center certification for medical devices)

🞏 If the product is at the research and development (R&D) stage, provide related safety testing plan.....

9.1.5 Other, e.g., robotics applications, exercise programs, manuals, teaching methods.

Details of the intervention provided: ..........................................

9.2 Specify the method of administration, dosage, and duration, e.g., take twice a day, 1 tablet per dose, before meals in the morning and evening, etc………………………………………………

**10. Study procedures**

*(Specify the details of the research process, tools to be used in the research, and the steps used in conducting the research. You must also specify the number of appointments, the participants needed for treatment, and the time to be spent with each treatment. A flow chart is recommended for complex procedures)*

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**11. Study site**

❏ Single center (Data collectors are part of a single research team)

❏Single site (collecting data from only one location) at…………..

❏Multi-sites (data are collected from multiple locations) including ………………………

❏ Multi center

❏ In Thailand only, please specify research sites \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Specify all institutions participating in the research project. Include the number of research participants and the results of the Ethics Committee review for each institute)*

❏ Multinational project, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Specify countries participating in the research. Include all institutions in Thailand, number of research participants, and the results of the Ethics Committee review for each institution in Thailand)*

**12.** Will biological samples and/ or data, be transferred to, or received from other institutions outside Mahidol University?

**❏ No**

**❏ Yes (***If yes, please attach a copy of the signed Material Transfer Agreement (MTA), or Data Sharing Agreement (DSA) for consideration. MTA and DSA MU templates can be found on* **https://sp.mahidol.ac.th/th/MTA-DSA/index.html)**

**❏ PI is the provider.** The biological samples (or data) will be sent to*…(please indicate the recipient institution)…………*

**❏ PI is the recipient.** The biological samples (or data) will be received from *…(please indicate the provider institution)…*

**13. Data Sharing with other researcher/sponsor/or organization**

**❏ No ❏ Yes (The MU DSA Form can be downloaded here https://sp.mahidol.ac.th/th/MTA-DSA/index.html)**

**14. Duration of the study**

Full project duration\_\_\_\_\_\_\_\_\_\_\_\_months \_\_\_\_\_\_\_\_\_\_\_\_years

Period of data collection from study participants \_\_\_\_\_\_\_\_\_\_\_\_ years \_\_\_\_\_\_\_\_\_\_\_\_ months *(You can start collecting data after the project has been approved by the Ethics Committee)*

**15. Data collection process**

*\* Please fill in the information briefly*. *Please attach the Case Record form, Questionnaire, Interview plan or other tools for consideration.*

*\* For all types of data records used in research, participants must not specify their first-last names, Hospital Number (HN), or other identification that can identify individual participants / volunteers. Use an anonymous code instead.*

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**16. Outcome measurement/Data analysis**

* **Primary outcome** *(Please state what the main results of this study are that will be used to calculate the sample size.)*
* **Secondary outcome (if any) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* **Assessment of efficacy\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* **Assessment of safety\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
* **Statistics to be used or process for data analysis\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**17. Recruitment process**

**- Place of recruitment**

❏ Organization/Agency, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ❏ Community/ Public area, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**- Requesting permission to enter place of recruitment**

❏ Necessary to requesting permission, please specify the authorized person \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Except for requesting permission because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**- Requesting permission to use data/information or biospecimens**

❏ Not applicable

❏ Necessary to requesting permission, please specify the authorized person \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

❏ Except for requesting permission because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**- Please explain the recruitment process in detail; who will be the recruiter, and the recruitment method\_\_\_\_\_\_\_\_\_\_\_\_**

*If a potential subject has a dependent relationship with the recruiter, such as patient – doctor, it is recommended that other well-trained personnel perform this function to prevent undue influence.*

**- Will any recruitment material be used?**

**❏ Yes** *(Please specify the type of recruitment material, e.g. poster, brochure, and attach a copy of the material for IRB consideration)* **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**❏ No**

**18. Informed consent process (describe the process to obtain the Informed Consent from the participants):**

18.1 Immediately after the recruitment process❏yes ❏ no, please go to item 18.2

18.2 If not immediately after the recruitment process, please give the duration between recruitment and the informed-consent process \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Who will provide the information to obtain the informed consent from the participants? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

18.3 Participant Information Sheet (PIS) and Informed Consent Form (ICF) (Prepare the PIS and ICF as separate documents)

Please select:

❏ For a competent adult (18 years or older)

❏ For an incompetent adult (mentally ill or unconscious) the documents are prepared for a legally authorized representative to read and sign *(Prepare the Participant Information Sheet and Informed Consent Form for the Legally Authorized Representative to read and sign, to document the participant’s consent to participate in the research)*

Documents for minors (less than 18 years of age)

❏ Less than 7 years of age *(prepare the Participant Information Sheet and Informed Consent Form for parents or legal guardians)*

❏ Participant(s) aged 7-12 years:

* prepare the Participant Information Sheet & Informed Consent Form for parents or legal guardians
* prepare the Participant Information Sheet and Informed Assent Form for minors using appropriately simplified language

❏ Participant aged 13-17 years *(prepare the Participant Information Sheet and Informed Consent Form for parents or legal guardians, and include a signature space for minors to co-sign with their parents or legal guardians)*

**18.4** Request for **waiver of informed consent documents**

❏ 1. Written informed consent in the signed participant information sheet

❏ 2. Informed consent process by other means, please specify………………. (for example; checkbox as  in the questionnaire, verbal consent)

❏ 3. Waiver of informed consent document

For the answer in number 2. or 3., request for waiver or informed consent documents, please explain the reason: ……………………………………………………………………………………………………….……………………

\*\*Waiver of documentation of consent depends on IRB approval

**The explained reasons should include these following concerns:**

1. Is it true that the written informed consent document would be the only record linking the participant to the research, this identifiable data would be the participant’s harmful cause if a breach of confidentiality occurs? Why is that?
2. Is it true that the waiver or alteration will not adversely affect the rights and welfare of the participant? Why is that?

3) Is it true that the research cannot be carried out without waiver of participants’ consent? Why is that?

4) Is it true that the participants would be provided with additional information about their participation? How would they retrieve such information?

**19. Ethical Consideration**

**19.1 Reasons to experiment on human subjects**

*(Please explain why the research project needs to be conducted with human subject(s). Specify the research question and research problem. Explain how much data from previous studies are available.)*

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**19.2 Possible benefits from the research project**

*(Describe the possible benefits of the study to both individual research participants and overall society, including the benefits to participants in this study after the project ends. Explain briefly.)*

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**19.3 Foreseeable risk of injury associated with this research**

19.3.1 Provide information from previous study/studies about the severity and probability of adverse events

*(Please provide details and how often the serious adverse events have been reported)*

19.3.2 Plan to manage serious adverse events

19.3.3 Responsibility for research-related injury *(In the case of students, include the name and address of the Principal Advisor)*

19.3.4 Contact person in case of serious adverse event(s) *(In the case of students, include the name and address of the Principal Advisor)*

19.3.5 For clinical research. *(How can the Principal Investigator provide information about the research participation to the subject’s family doctor?)*

**19.4 Reference for safety** *(Provide cited references or information showing that the study would be safe and/or beneficial to the study participants. References should be written in the reference format.)*

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**19.5 Privacy and Confidentiality Protection**

Please indicate below how the PI will protect the privacy and confidentiality of the research participant(s)

❏ Using a coding system to protect the personal information/ data of the research participants in the Clinical Record Form

❏ Recording information by ❏ Photograph ❏ VDO ❏ Audio recorder

Specify who has access to the information, the data retention period, and how the information will be disposed of after the storage period\_\_\_\_\_\_\_\_\_\_\_\_

❏ Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| Please note that the Principal Investigator is requested to conduct a risk assessment of the project. Please use **Exemption Review Checklist or Expedited Review Checklist** to assess your protocol. If your project falls within the scope of one of the checklists, please attach it to the submission package for consideration. The Central IRB will re-evaluate it, and if it agrees with your assessment, your project will be considered accordingly. However, if it does not, your project will be considered subject to Full-Board Review |
| **20. Submitted documents**   * *Please send digital file via e-mail to:* [*mucirb@gmail.com*](mailto:mucirb@gmail.com) *Indicate the title of the research project and the sender’s contact information (name, address, telephone number, contact person, and e-mail address)* |

| **Sending** | **List of Documents** | **Please specify the file’s name as these recommendations** | **Attach File** |
| --- | --- | --- | --- |
| 0. **Risk Assessment of the Project** *(Please use the following checklists to classify the appropriate type of review.)* | | | |
| □ | Exemption Review Checklist | 0.Exemption Review Checklist | PDF |
| □ | Expedited Review Checklist | 0.Expedited Review Checklist | PDF |
| □ | This project is not classified as an Exemption or Expedited Review.  *(If the project is not classified as an exemption or expedited review, no checklist form is needed for submission)* | | |
| □ | 1. Submission Form | 1.Submission Form | PDF**\***, Word |
| □ | 2. Protocol/Proposal | 2.Proposal | PDF |
| □ | 3. Participant information sheet *(In the case of collecting with foreigners; please submit both English language and Local language.)* | 3.PIS/ Self-PIS  (if more than 1 group, please specify 3.1, 3.2 accordingly) | Word |
| □ | 4.Informed consent form *(In the case of collecting with foreigners; please submit both English language and Local language.* | 4.ICF | Word |
| □ | 5.Principal Investigator’s Curriculum Vitae and Co-Investigators | 5.CV  (if more than 1 person, please specify 5.1, 5.2 accordingly) | PDF |
| □ | 6. Certificate of attendance for human subject protection training or registration in human subject protection course approved by the Faculty of Graduate Studies of Principal Investigator and Co-Investigators | 6.Certificate  (if more than 1 person, please specify 6.1, 6.2 accordingly) | PDF |
| □ | 7. Research tools: case record form, questionnaire, interview guide, etc. *(In the case of collecting with foreigners; please submit both English version and Local language version. )* | 7.Questionnaire/Interview guide/ Case record form/ (if more than 1 document, please specify 7.1, 7.2 accordingly) | PDF |
| □ | 8. Recruitment materials (if any)  *(In the case of collecting with foreigners; please submit both English version and Local language version.)* | 8.Poster/ Recruitment Material  (if more than 1 document, please specify 8.1, 8.2 accordingly) | PDF |
| □ | 9. Request for permission to collect data | 9. Document’s name (if more than 1 document, please specify 9.1, 9.2 accordingly)) | PDF |
| **If the researcher is a student, please attach the following additional documents.** | | | |
| □ | 10. GR.1 Thesis title and thesis advisory committee | 10. GR.1 | PDF |
| **Drug trial** | | | |
| □ | 11. Drug information   * For registered drug, please attach the official document issued by Food and Drug Administration, Ministry of Public Health or the drug leaflet * If the drug has not yet been registered, please attach the document declaring that the purpose of the imported drug as for clinical research, along with the investigator brochure | 11.Document’s name | PDF |
| **Medical device** | | | |
| □ | 12. Information of the medical device   * For registered medical device, please attach the official document * If the medical device has not yet been registered, * Please specify the materials and specifications * Please attach the safety information such as laboratory tests, production system, quality control * Please attach the document for import of medical device (issued by Ministry of Public Health) | 12. Document’s name | PDF |
| **Foods / dietary supplements** | | | |
| □ | 13. Foods / dietary supplements   * For registered products, please provide the food product identification number, issued by Food and Drug Administration * If the product has not yet been registered, and it needs to be imported, please attach the import form * If the product has not yet been registered, and it can be domestically produced, please attach the form | 13. Document’s name | PDF |

**21. Commitments**

1. I, as the principal investigator, and my co-investigators, as listed and signed in this document, will conduct this study according to the protocol approved by MU-IRB. I will conduct the informed consent process by providing adequate information, as approved, and provide sufficient opportunity to potential subjects to consider whether or not to participate, with respect for the person, without coercion or undue influence.
2. I will obtain pre-approval of any changes in the research activity and inform the research subjects about the change for their consideration to continue participating in the study.
3. I will report to the MU-IRB all serious adverse events and unanticipated events and will do my best to help the research subjects in such cases.
4. I will provide reports concerning the progress of the research annually or upon request.

I and my co-investigator have adequate knowledge and training in the procedural intervention needed while conducting this research and providing care for any research-related injury to the research subjects.

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| **Signature of Principal Investigator**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  **Date** \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ | **Signature of Co-investigator**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  **Date** \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ |
| **Signature of Co-investigator**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  **date** \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ | **Signature of Co-investigator**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  **date** \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ |
| **22. Permission from Thesis Advisor/ Direct Superior Authorized to Approve the Research Project**  **Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Thesis Advisor/ Direct Superior Authorized to Approve Research Projects**  (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  **Date** \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_ | |