**Part 1: Checklist in determining whether a research is human subject research and requires ethical approval.**

A research project means systematic research aimed at creating knowledge or know-how (Systematic Investigation) and new understandings that can be widely disseminated and utilized (Generalizable Knowledge). (According to the Announcement of King Mongkut's University of Technology Thonburi on the Supervision of Human Research B.E.2559 (2016))

\*If your answer is ‘Yes’ in any item, **go to Part 2.**

\*If your answer is ‘No’ in all items, your research study is not considered as human subjects research (Non-Human Research). Nonetheless, it may be submitted to KMUTT IRB for receiving a written confirmation that it is a non-human research project.

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| **Researcher’s opinion** | **SubCommittee’s opinion** | **Research Project** **(Please ✓ in the items that apply to your research study.)** | **Committee’s remark** |
| ☐ Yes☐ No | ☐ Yes☐ No | 1.Research directly or indirectly involving communication and interaction with participant through educational research, classroom research questionnaire, survey questions, and interviews whether in-person, phone, mail, email, use of media/devices, monitoring/observing behavior or other web applications, the research study on medical records or database or other.  |  |
| ☐ Yes☐ No | ☐ Yes☐ No | 2.Research involving data collection process (follow-up/observation), information request process, and research procedure that physically, psychologically or privately affects participants, those who are not the Principal Investigator and Co-Principal Investigator. |  |
| ☐ Yes☐ No | ☐ Yes☐ No | 3.Research involving the use of unidentified human biological products such as cell culture or mucus (blood, urine, sweat, etc.) or feces. Can identify or identify the person who owns it. Are they used in research projects?  |  |

**Part 2: Research Participants**

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| **Researcher’s opinion** | **SubCommittee’s opinion** | **Research Project** **(Please ✓ in the items that apply to your research study.)** | **Committee’s remark** |
| ☐ Yes☐ No(If your answer is ‘No’, go to Part 3) | ☐ Yes☐ No | Participants of the research study are in the vulnerable subjects.\*\*\* Vulnerable subjects are Infants, children, minors (under 20 years old), pregnant women, subordinates e.g. students, staff, officers, patients with contagious illness/chronic illness, prisoners, alien workers, ethnic group, minority group, reading/writing disabilities, people in shelters, such as orphans and the elderly If your answer is ‘Yes’, do not complete Part 3. You must complete IRB Form-02 for an Expedited/Full Board review. |  |

**Part 3: Research project review form for human research ethics assessment**

| **Researcher’s opinion** | **Research Project** **(Please ✓ in the items that apply to your Research study.)** | **SubCommittee’s opinion** |
| --- | --- | --- |
| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 2) | **1. Educational Research** | ☐ Yes☐ No |
| ☐ Yes | **1.1 Research involving the following: (Please complete IRB Form-01 for an Exemption review)** * **Normal Educational Practice and Setting**
* Comparative study of different types of instructional methods.
* Comparative study on the effectiveness of teaching techniques and classroom management or comparative study between different study programs.
* Commonly accepted research methods and/or conduct during normal educational practices.
* Does not cause participants to lose their learning opportunities or affect their learning assessment.
* **Educational Test**

Research involving educational tests, such as cognitive test, aptitude test, diagnostic test, or achievement test. |
| ☐ Yes | **1.2 Research involving the following: (Please complete IRB Form-02 for an Expedited/Full Board review)** * New method that has never been used before.
* Students in the same classroom are treated differently.
* Some information is hidden from the participants.
* Excessive exercise or abnormal method of exercising.
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| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 3) | **2. Survey research, interviews, public behavior observation** | ☐ Yes☐ No |
| ☐ Yes | **2.1 Research involving the following: (Please complete IRB Form-01 for an Exemption review)** * Surveys, interviews, questionnaires, or behavioral observations within communities, and the collected data cannot be linked to personal data directly or indirectly, and the results will be reported as a general overview.
* Collecting data from participants by answering questions verbally or in writing, which is not harmful, takes a short period of time, does not cause pain or embarrassment, and does not have significant negative effects in the long term.
 |
| ☐ Yes | **2.2 Research involving the following: (Please complete IRB Form-02 for an Expedited/Full Board review)** * survey, interview, or observation used may be sensitive and cause emotional and psychological trauma.
* any disclosure of the human subjects’ responses could reasonably place the subjects at risk of criminal or civil liability
* any disclosure that could cause loss of benefits or be damaging to the subjects’ credibility, financial states, employability, reputation or the opportunity for further education.
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| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 4) | **3. Collection or Study of Existing Data (Documents or Records)** | ☐ Yes☐ No |
| ☐ Yes | **3.1 Research involving the following: (Please complete IRB Form-01 for an Exemption review)** * Unidentified data or tissues means it is initially not coded or cannot be identified.
* Specimens or tested products (e.g. blood) have been previously collected, not newly collected and the data must be anonymized.
* Publicly available.
* The data collected by researchers has nothing to do with individuals, and the researchers will not contact the data owner or reveal the identity of the data owner.
* Data collection and analysis related to health care processes or public health activities.
* The government collects data for its purposes other than research.
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| ☐ Yes | **3.2 Research involving the following: (Please complete IRB Form-02 for an Expedited/Full Board review)** * Identified data or tissue sample from previous project even though the investigator informed not to record any personal information
* Identified tissues owners from previous pathological collection.
* Data from previous research activities.

\*\*\* The PI must obtain permission to use data/tested sample products/ e.g. from Hospital Director. |
| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 5) | **4. Quality Assurance, Public Benefit or Service Program** | ☐ Yes☐ No |
| ☐ Yes | **4.1 Research involving the following: (Please complete IRB Form-01 for an Exemption review)** * Research related to quality assessment; Evaluate service providers' satisfaction with institutional services, so as to improve the internal performance quality of institutions, especially matters related to public interests.
 |
| ☐ Yes | **4.2 Research involving the following: (Please complete IRB Form-02 for an Expedited/Full Board review)** * The collected data can directly or indirectly identify the data owner.
* Research publication may cause harm to data owners, such as losing certain public service opportunities.
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| ☐ Yes☐ No   | **5. 5. Taste and Food Evaluation and Acceptance Study** | ☐ Yes☐ No |
| ☐ Yes | **5.1 Research involving the following: (Please complete IRB Form-01 for an Exemption review)** * Food does not contain any additives.
* Food ingredient must be at safety level.
 |
| ☐ Yes | **5.2 Research involving the following: (Please complete IRB Form-02 for an Expedited/Full Board review)** * Food that contains additives that are at or below the level found to be safe by the Food and Drug Administration.
* Food that contains chemical contaminants from agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration.
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| **For Principal Investigator (PI)**1. The Principal Investigator can use IRB-Checklist in determining whether the activity is human subjects research and required ethical approval, but the IRB Committee’s decision is the final.
2. If the Principal Investigator believes that the study is considered for’ Exemption review (if your answer is ‘Yes’ in any item in the Form), you must complete IRB-Form-01 for ethical approval from the IRB Committee.
3. If the study is not considered for Exemption Review (when your answer is ‘No’ in all items in the Form), you must complete IRB-Form-02 for ethical approval from the IRB Committee.

“The IRB Committee has the right to consider the types of reviews and may request documents if necessary or incorrectly submitted which may affect the length of period.Signature ……………......………………….(…………………………….....................…………….IN PRINT)Date: …………………………………. |

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| **For IRB Subcommittee of Faculty/Office/** **Institution**  |
|  **🞎 Eligible for Exemption Review** Other comments: …………….…………………………………………………………………………………………………………………………..….. **🞎 Eligible for Expedited Review** Other comments: …………….…………………………………………………………………………………………………………………………..….. **🞎 Eligible for Full-Board Review** Other comments: …………….…………………………………………………………………………………………………………………………..….. **🞎** **Non-Human Research** Other comments: …………….…………………………………………………………………………………………………………………………..….. 🞎 Other …………………….……………………………………………………………Signature ……………………………………………. (IRB Subcommittee) Date: ……….....……….. |
| **For IRB Committee** |
|  **🞎 Eligible for Exemption Review** Other comments: …………….…………………………………………………………………………………………………………………………..….. **🞎 Eligible for Expedited Review** Other comments: …………….…………………………………………………………………………………………………………………………..….. **🞎 Eligible for Full-Board Review** Other comments: …………….…………………………………………………………………………………………………………………………..….. **🞎** **Non-Human Research** Other comments: …………….…………………………………………………………………………………………………………………………..….. 🞎 Other …………………….……………………………………………………………Signature ……………………………………………. (IRB Secretary) Date: ……….....……….. |