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

\*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.

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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 involving data collection process (follow-up/observation), information request process, and research procedure that physically and psychologically affects the research participants. Those who are not the Principal Investigator and Co-Principal Investigator.
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| ☐ 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, or other web applications.
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| ☐ Yes☐ No | ☐ Yes☐ No | 1. 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?
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**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 not in the vulnerable subjects.\*\*\* Vulnerable subjects are children (under 13 years old), pregnant women, subordinates, patients with contagious illness/chronic illness, prisoners, alien workers. If your answer is ‘Yes’, do not complete Part 3. You must complete IRB Form-02 for an Expedited/Full Board review. |  |

**Part 3: Exemption Review Checklist**

(If your answer is ‘Yes’ in any item, your research study is human subjects research and subject to an Exemption Review. You must complete IRB Form-01).

| **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 item no. 2) | ☐ Yes☐ No | 1. Educational Research
	1. 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.
	1. Research involving educational tests such as cognitive test, aptitude test, diagnostic test, or achievement test.

-----------------------------------------------------------------------------------**unless** it is research involving the following:* 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.

☐ Yes ☐ No **(You must complete IRB Form-02 for an Expedited/Full Board review)**  |  |
| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 3) | ☐ Yes☐ No | 1. Research involving the use of survey procedures, interview procedures or observation of community behavior or other collected data in which subjects cannot be directly or indirectly identified and report as individual and the overall results,

------------------------------------------------------------------------------------**unless** it is research involving the following:* 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, or reputation.

☐ Yes ☐ No **(You must complete IRB Form-02 for an Expedited/Full Board review)**  |  |
| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 4) | ☐ Yes☐ No | 1. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are publicly available with the following characteristic:
	* 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.

-----------------------------------------------------------------------------------**unless** it is research involving the following:* + 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 (**You must complete IRB Form-02 for an Expedited/Full Board review)**  |  |
| ☐ Yes☐ No(If your answer is ‘No’, go to item no. 5) | ☐ Yes☐ No | 1. Quality Assurance, Public Benefit or Service Program: Research involving quality assurance, public benefit or service programs, satisfaction programs, and procedures for obtaining benefits of those programs.
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| ☐ Yes☐ No | ☐ Yes☐ No | 1. Taste and Food Evaluation and Acceptance Study
* Food does not contain any additives.
* Food ingredient must be at safety level.

----------------------------------------------------------------------------------------**unless** it is research involving the following:* 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.

☐ Yes ☐ No (**You must complete IRB Form-02 for an Expedited/Full Board review)**  |  |

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| **For Principal Investigator (PI)**1. The Principal Investigator can use IRB-Checklist-01 in determining whether the activity is human subjects research and required ethical approval, but the IRB Committee’s decison 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: …………………………………. |
| **For IRB SubCommittee** | **For IRB Committee** |
| Signature …………………………………….(…………….........................…………………………IN PRINT)IRB SubCommittee, Faculty/Institution: ………………………………Date: …………………………………….………. | Signature ………………………………………….(………………………....................................………………IN PRINT)IRB SecretaryDate: ……….……………………………………. |