IRB Review of Human Subjects Research - Exemption
Complete the following to determine
If the proposed study meets one or more categories for exemption

Researcher's opinion (Y/N)	Committee's opinion (Y/N)	Research Category	Committee's remarks
		1. Educational research and practices **1.1) Research conducted in established or commonly accepted educational setting, involving normal educational practices, such as:** - Research on regular and special education instructional strategies - Research on the effectiveness of or comparison among instructional techniques, classroom management methods, and curricula. - Commonly accepted research methods - Conduct during normal educational practices **1.2) Research involving the use of educational tests such as cognitive, aptitude, diagnostic, achievement unless:** - Unestablished or unrecognized research method - Different treatments applies to same class students - Undisclosed information to research subjects - Excessive activities, exercises, or uncommonly accepted method	
		2. Survey, interview or observation of public behaviors: research involving the use of survey procedures, interview procedures, or observation of public behavior that subjects cannot be directly or indirectly identified unless: - Survey, interview, or observation used may be insensitive and emotional and psychological trauma - Any disclosure of the human subjects responses could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation	

Researcher's opinion (Y/N)	Committee's opinion (Y/N)	Research Category	Committee's remarks
		3. Collection or study of existing data (documents, records): research involving the collection or existing data, documents, records, pathological specimen, and if these sources are publicly available or accessible - The information is recorded by the investigator in a manner that subjects cannot be identified directly or through identifier linked to the subjects - Specimen must be previously collected with subjects' information removed	
		4. Quality assurance, public benefit or service program - Research related to quality assurance, public benefit or service programs, satisfaction programs, and procedures for obtaining benefits of those programs	
		5. Taste and food evaluation and acceptance study includes natural products and contains safe ingredients unless: - If wholesome foods with additives are consumed - If a food is consumed that contains a food ingredients at or below the level for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration	

Note:

1) Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact IRB concerning the status of proposed research
2) IRB Exemption form must be submitted for exemption determination
3) Exemption consideration will only be made by IRB committees
4) No research can begin until Certificate of Exemption (COE) is issued

❖ Definition

Exempt

A research is **exempt from meeting requirements for initial and continuing IRB review**. Research that is found to be "exempt" is **still considered to be human subject research**.

Minimal risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Deception means deliberately misleading subjects about some aspect of the research.

Examples of deception include:

- Misinforming participants about the research
- The use of fake or rigged instruments or procedures
- Misleading play-acting in experimental design
- The use of covert procedures

Incomplete disclosure means deliberately withholding certain information regarding certain aspects of the study. Examples include: Withholding specific information about the true purpose of a study.

Studies using deception or concealment may qualify for exempt status when all applicable exempt criteria are met and when:

- The deception or incomplete disclosure is necessary to ensure valid results or to reduce biased responses and such deception is not harmful to subjects.
- The deception or incomplete disclosure is not being used to get subjects to do something that the majority of them would not do *if the information was fully disclosed to them*; and
- The conditions of the deception pose no more than minimal risk of physical or emotional distress. "Conditions" include: the nature of the deception or concealment; how likely it is that subjects will learn of the deception or concealment; the nature of any de-briefing; how likely it is that anyone besides the research team and the subject would learn results about a subject that would be distressing to the subject.
- A debriefing of subjects after they complete the procedures may be appropriate and may be required (but is not necessary) to obtain exempt status. The need for a de-briefing does not necessarily exclude a project from exempt status; the key issue is whether the project overall (including the de-briefing) involves no more than minimal risk to subjects.