Machine Translated by Google

Announcement of the Central Committee for the Ethics Review of Human Research.

The topic is "Research projects involving humans that are exempt from committee review."

……..

In order to expedite the review process of research projects and reports while still protecting the rights, safety, and well-being of research participants, the Central Ethics Committee for Human Research in Thailand has established the following guidelines:

Criteria for research involving humans that qualify for exemption from the Central Ethics Committee for Research.

Based on the criteria of the US Department of Health and Human Service and without age restrictions for research participants, as follows:

1. The following items are not eligible for exemption:

1.1 Research in children that involves educational testing in children or observation of public behavior by...

1.2 Researchers participated

in research involving individuals that are required by law or regulations of any government agency.

Subject to review by the research ethics committee.

1.3 Research with the following groups of people:

A. Teenage mothers

B. Those who are illiterate.

C. Critically ill patients.

d. Research on individuals with decision-making impairments, such as those with mental disabilities.

Intelligence or memory. Marginalized

groups such as refugees/migrants, ethnic groups, homeless people, and vagrants.

f. Elderly people in welfare institutions.

C. Prisoners or detainees.

2. The following human research studies may receive an exemption.

2.1 Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not

Machine Translated by Google

likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2.2 Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

2.3 (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

Machine Translated by Google

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

2.4 Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under laws for the purposes of “health care

Machine Translated by Google

operations” or “research”; or

2.5 Research and demonstration projects that are conducted or supported by a Thai government department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

2.6 Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe according to Ministry of Health or Ministry of Agriculture.

And add the following exceptions to the list above:

1. Research on cadavers/cadavers that have received consent from the owner or their relatives for research purposes. In writing.

Announced on June 15, 2020.

(Professor Emeritus Dr. Thada Sueblinwong)

Chairman of the Board of Directors, Foundation for the Promotion of Human Research in Thailand.

Director of the Central Ethics Committee for Human Research.