



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

Regarding "Research Projects/Research Reports Eligible for Expedited Review".

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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:

The criteria for research that can be submitted for expedited review are based on the US Department of Health and Human Security guidelines.

Human Service and without age restrictions for research participants, as follows:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children,² considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
2. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than



routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/ approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
4. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.



7. Continuing review of research previously approved by the convened IRB as follows:

- (a) Where (i) the research is permanently closed to the enrollment of new subjects;
 - (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
- (b) Where no subjects have been enrolled and no additional risks have been identified; or
- (c) Where the remaining research activities are limited to data analysis.

8. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

And in addition to the above, as follows:

- 1. Research conducted using leftover specimens/surplus blood samples that still contain identifiable information (if there is no information, it qualifies as exempt).
- 2. The project involves storing biological samples in a repository; these are leftover/surplus specimens from routine diagnostic testing that still have identifiable information (if there is no information, they are exempt).
Broad consent is required.
- 3. Research involving mild behavioral intervention in adults.
- 4. Certain types of research cannot be exempted because they involve the collection of specific information.
Identifiable private information or code-linked information.

However, the following research cannot be considered urgent:

- A. The environmental context in which the research project is conducted poses risks to the research.

The number of people who will participate in the research has increased to the point where it poses a slight risk.

- B. Research on sensitive issues affecting family, community, society, or law, where disclosure is required.

Individuals and/or information provided by individuals are likely to put them at risk of civil or criminal penalties.



Criminal conduct, financial status, employment, insurance, occupation, or potential discrimination or defamation, unless appropriate measures are taken to protect privacy and maintain confidentiality to the point where the risk is reduced to a level no higher than a small risk. C. This research is conducted

on the following groups of individuals: 1)

adolescent mothers,

2) illiterate individuals, 3)

critically ill patients,

4) individuals with impaired decision-making abilities, such as those with mental or intellectual disabilities.

Or memories.

5) Marginalized groups, such as refugees/migrants, ethnic groups, the homeless, and the vagrants.

6) Elderly people in welfare

institutions. 7) Prisoners or inmates.

Announced on June 15, 2020.

A handwritten signature in black ink, which appears to read "Thada Sueblinwong". The signature is written in a cursive, flowing style.

(Professor Emeritus Dr. Thada Sueblinwong)

Chairperson of the Executive Committee of the Foundation for the Promotion of Human Research in

Thailand, and Supervisor of the Central Committee for the Review of Human Research Ethics.