AF 05-09/1.0



**Criteria for Expedited Review of Research Protocol**

**by Naresuan University Regional Research Ethics Committee**

**Expedited review** is a review process set by the board to review protocol (DHHS, FDA).

1. Expedited review will be conducted by chair or experienced board member whom appointed by chair.
2. Applicability:
   1. The research activities that present no more than minimal risk.
   2. If identification of the subjects or their responses place them at risk, the reasonable and appropriate protection must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
   3. Minor changes in previous approved research which no additional risks involved.
   4. Recruitment materials which the standard requirements of informed consent have been applied.
   5. Research activities that are not directly involved with living human e.g. study of donated organs or bodies.
3. Research activities that involve procedures listed in the following categories may be reviewed through expedited review process.
   1. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from healthy, non-pregnant adults who weigh at least 50 kg (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.
   2. Blood samples taken from volunteers other than 3.1, age, weight, and health condition of the volunteers must be considered. In general, 3 ml/kg body weight within 8 weeks and collection not occur more frequently than 2 times per week is possible; however, total blood quantity should not exceed 50 ml.
   3. Prospective collection of biological specimens for research purposes by noninvasive means e.g. hair or nail clipping in a non-disfiguring manner, teeth if routine patient care indicates a need for extraction, external secretion (incl. sweat), placenta removed at delivery, amniotic fluid obtained at the time of rupture of the membrane prior to or during labor, mucosal and skin cells collected by buccal swab or scraping or mouth washing, sputum collected after saline mist nebulization, etc.
   4. Collection data through noninvasive procedures routinely employed in clinical practice (excl. x-rays or microwaves) e.g. physical sensors that are applied either to amounts of energy into the subject or an invasion of the subject’s privacy, magnetic resonance imaging, ECG, EEG, ultrasound, Doppler blood flow, echocardiography, moderate exercise, body composition measurement.
   5. Examining materials (data, records, documents, specimens) that have been collected or will be collected solely for non-research purposes (such as medical diagnosis or treatment).
   6. Collection of data from voice, video, digital, or image recordings made for research purposes.
   7. Research on individual or group behaviors or research employing survey, interview, oral history, focus group, program evaluation, or quality assurance methodologies.
   8. Continuing review of protocol previously approved without non-compliance/deviation/violation.
   9. Protocol amendment with which no additional risks have been identified.
4. Expedited reviewers can exercise all of the authorities of the board except disapproval. Expedited reviewers may approve the protocol or refer to the full board otherwise.