Criteria for Expedited Review

Your research may qualify for an expedited review if one or more of the following criteria apply:

Please check all boxes that you believe may apply.

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|  | Research will not involve animals. Note: Research involving animals requires a full review that includes a review by the Institutional Animal Care and Use Committee (IACUC). Research involving animals may also be subject to federal and state regulations under the Animal Welfare Act, and periodic review and inspection by the USDA. It is the responsibility of the PI to ensure that the research project meets all applicable state and federal regulations. Copies of all materials, such as letters of inspection and licenses, must accompany this application. |
|  | Research will not involve children under 18. Northern Oklahoma College does not support research projects involving participants under the age of 18 with the exception of proposals fitting the “exempt” status. |
|  | Research does not involve studies of drugs and medical devices unless both of the criteria below are met.   1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increase the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) 2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
|  | Research does not involve collection of blood samples by finger stick, heel stick, ear stick, or venipuncture unless the two following criteria are met:   1. From healthy, non-pregnant 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 2. From other adults and children, 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 2 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. |
|  | Research may involve 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, or mouth washings; (j) sputum collected after saline mist nebulization. |
|  | Research will involve 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 age, weight, and health of the individual. |
|  | Research may involve animals (data documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). |
|  | Research may involve collection of data from voice, video, digital, or image recordings made for research purposes. |
|  | 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. |
|  | Continuing review of research previously approved by the convened IRB as follows:   1. 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 2. Where no subjects have been enrolled and no additional risks have been identified; or 3. Where the remaining research activities are limited to data analysis |
|  | 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 by 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. |

Note: These categories represent minimal requirements of review by 45 CFR 46. The NOC Institutional Review Board reserves the right to require a more stringent review of any study as deemed appropriate.