|  |  |
| --- | --- |
|  |  |

|  |
| --- |
| **Expedited Categories** *(Select all that apply)* |
| **[ ]**  | 1(a)  | Clinical studies of drugs when *an IND is not required*. |
| **[ ]**  | 1(b) | Clinical studies of medical devices when *an IDE is not required*, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
| **[ ]**  | 2(a) | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture[[1]](#endnote-1) from healthy, non-pregnant adults who weigh >110 pounds where the amount drawn does not exceed 550 ml in an 8 week period and collection occurs no more frequently than 2 times per week[[2]](#endnote-2). |
| **[ ]**  | 2(b) | Collection of blood samples by finger stick, heel stick, ear stick, or venipunctureii from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected may not exceed 50 ml or 3 ml per kg in an 8 week period, and collection occurs no more frequently than 2 times per weekiii. |
| **[ ]**  | 3 | Prospective collection of biological specimens for research purposes by noninvasive[[3]](#endnote-3) means.[[4]](#endnote-4) *(Examples: placenta removed at delivery; sputum collected after saline mist nebulization; mucosal and skin cells collected by buccal scraping or swab, or mouth washings; hair and nail clippings in a non-disfiguring manner)* |
| **[ ]**  | 4 | Collection of data through noninvasive proceduresiv (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.[[5]](#endnote-5) *(Examples: weighing or testing sensory acuity, MRIs, ECGs, ultrasound, moderate exercise; muscle strength testing)* |
| **[ ]**  | 5 | Research involving materials (data, documents, records, or specimens) that have been collected for any purpose or will be collected solely for non-research purposes. |
| **[ ]**  | 6 | Collection of data from voice, video, digital, or image recordings made for research purposes. |
| **[ ]**  | 7 | Research on individual or group characteristics or behavior[[6]](#endnote-6) *(Examples: research on perception, cognition, motivation, identity, communication, social behavior, beliefs)* **OR** research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies that did not meet an exemption category. |
| **[ ]**  | 8(a) | **Continuing review of research** previously approved by the convened IRB 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. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.) |
| **[ ]**  | 8(b) | **Continuing review of research** previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source. |
| **[ ]**  | 8(c) | **Continuing Review of Research** where the remaining research activities are limited to data analysis. |
| **[ ]**  | (9) | **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. |

1. Withdrawal of blood from an indwelling venous line is a “venipuncture.” [↑](#endnote-ref-1)
2. Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure. [↑](#endnote-ref-2)
3. Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares. [↑](#endnote-ref-3)
4. Examples: (a) hair and nail clippings in a non-disfiguring 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 gum-base 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. [↑](#endnote-ref-4)
5. 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. [↑](#endnote-ref-5)
6. Examples: 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. [↑](#endnote-ref-6)