ARROWHEAD REGIONAL MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

EXPEDITED REVIEW CATEGORIES

Expedited review means that the proposed research is reviewed by the IRB chair, or a designated voting member, rather than by the entire IRB. Expedited review is permitted for certain kinds of research involving no more than minimal risk. The Chair or designee is responsible for final determination of type of review. The IRB retains the right to require full board review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

Criteria for Expedited Review

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. Standard requirements for informed consent (or its waiver, alteration, or exception) apply. The activities listed are not necessarily minimal risk. Inclusion on the list merely means that the activity is eligible for expedited review when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. ***If you believe your project meets criteria for the expedited review, please check all categories below that apply.***

1. **Clinical studies of approved drugs and medical devices**
   Research on drugs for which an investigational new drug application (IND) is not required (21 CFR Part 312). (Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review) AND Research on medical devises for which (a) an investigational device exemption application (IDE) is not required (21 CFR Part 812); or (b) the medical device is cleared/approved for marketing the medical device is being use in accordance with its cleared/approved labeling.

2. **Collection of blood samples**
   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, 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, considering age, weight, and health, the collection procedure, the amount of blood to be collected, and 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/kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. **Collection of biological specimens**
   Prospective collection of biospecimens for research purposes by noninvasive means.

   Examples include: (a) hair and nail clippings, in a nondisfiguring manner; (b) deciduous teeth at the time of exfoliation; (c) permanent teeth if patient care indicates a need for extraction; (d) collection of excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or 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) collection of both supra- and subgingival dental plaque and calculus, provided the collection procedure 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

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4. **Collection of data through noninvasive procedures**
   Collection of data through non invasive 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.

Examples include: (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.

5. **Data, documents, records, or specimens collected for non-research purposes or secondary use**
   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). Some research in this category may be exempt from the HHS regulations 45 CFR 46.104(d). This category includes materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.

6. **Collection of voice, video, digital, or images**
   Collection of data from voice, video, digital, or image recordings made for research purposes. Expedited review does not apply if identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

7. **Surveys, interviews, evaluation, etc.**
   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. Some research in this category may be exempt from the HHS regulations 45 CFR 46.101(b)(2) and (b)(3).