FORM 2: Application for Expedited Review by UAH Institutional Review Board

Name: _____ Date: _____
Address:_____
City, State, Zip _____
Telephone: ( ) _____ UAH Email: _____
PI and Faculty Supervisor (if applicable):

Signature Date

Signature Date

Research conducted may receive expedited review by the UAH IRB if the research involves no more than minimal risk and fully meets at least one of the following (please check all that apply):

___ Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: 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. (b) 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.

___ 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, considering the age, weight, and health of the subjects, 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 per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

___ 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.

___ 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).

___ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

_____ 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.

I hereby certify that my research fully meets the categories indicated above. In the event that my research becomes ineligible for such expedited review, for any reason, I will re-apply for appropriate UHSC review.

_____
Signature Date

Checklist: *New, Expedited* Review Submission

(Rev. 03/2020)

Submissions must be saved in pdf format and sent to irb@uah.edu

☐ Completed and electronically signed IRB **Application for Expedited Review by UAH IRB**

☐ One copy of the signed **Institutional review board application (Form 1).**

☐ One copy of your **Consent Form.** If you wish to waive the required consent form, please state in your application why a waiver of consent is justified. Please see Consent Forms at www.uah.edu/irb. In order to waive consent, you need to meet the HHS guidelines

☐ For research involving children and/or minors **under 18 years of age,** one copy of a memorandum from the Principal Investigator which must address the Children's Risk Level assessment (see Form 6 at www.uah.edu/irb)

☐ Include instrument/surveys/questionnaires as applicable for review.

- **Make sure you have checked the IRB web page (http://www.uah.edu/irb) for the most current consent form format.**

Submit all materials in electronic form to irb@email.uah.edu.